

US3952173 (Prod: Synexus - Optimal Research - Rockville)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:31:39

All time stamps listed in this document are displayed in GMT

US3952173

Form: Participant Creation

Data signed: (b) (4) 08 Apr 2021 20:31:55

Generated On: 10 Jun 2021 10:31:39

[Participant ID](#)

US3952173

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

US3952173

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:16:26

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 22:16:23

Generated On: 10 Jun 2021 10:31:39

Date of Birth (MMM yyyy)	(b) (6) 1956
Age	64
Age Units	YEARS
Age (Derived)	64
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	False
Black	True
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

US3952173

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 22:16:26

Generated On: 10 Jun 2021 10:31:39

Date of Informed Consent (<i>dd MMM yyyy</i>)	29 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

US3952173

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 22:16:26

Generated On: 10 Jun 2021 10:31:39

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3952173

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 22:16:26

Generated On: 10 Jun 2021 10:31:39

Were any significant conditions reported?

Yes ☒
No ☐

US3952173

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 22:16:26

Generated On: 10 Jun 2021 10:31:39

Condition	HEPATITIS B
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3952173

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 22:16:26

Generated On: 10 Jun 2021 10:31:39

Condition	PROSTATE CANCER [IN REMISSION]
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

US3952173

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 22:16:26

Generated On: 10 Jun 2021 10:31:39

Condition	LEFT LEG SURGERY
Start date (dd MMM yyyy)	UN JUN 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN SEP 2000
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	SEP 2000
Stop Year (derived)	2000

US3952173

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 22:16:26

Generated On: 10 Jun 2021 10:31:39

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3952173

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 22:16:26

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 22:16:26

Generated On: 10 Jun 2021 10:31:39

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	29 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	12:43 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 12:43
Height (<i>xxx.x</i>)	69.0 in
Weight (<i>xxx.x</i>)	189.0 lb
BMI (<i>xxx.x</i>)	27.96878 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3952173

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 22:16:26

Generated On: 10 Jun 2021 10:31:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 SEP 2020

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

US3952173

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 22:16:26

Generated On: 10 Jun 2021 10:31:39

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

DISABLED, RETIRED VETERAN.
GROCERY SHOPS TWICE
WEEKLY.

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

PRODUCTION RELEASE (v12.003
EAB) (1725)

14 of 1797

US3952173

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 22:16:26

Generated On: 10 Jun 2021 10:31:39

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)	True
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

US3952173

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:16:26

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 22:16:26

Generated On: 10 Jun 2021 10:31:39

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

What was the participant's randomization number? 116016

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 ☒

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 22:16:26

Generated On: 10 Jun 2021 10:31:39

Height	ND - Not Done
Weight	ND - Not Done

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 22:16:26

Generated On: 10 Jun 2021 10:31:39

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 SEP 2020
Time of assessment (00:00-23:59)	12:43 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 12:43
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 22:16:26

Generated On: 10 Jun 2021 10:31:39

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 SEP 2020
Time of assessment (00:00-23:59)	15:30 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 15:30
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3952173

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 22:16:26

Generated On: 10 Jun 2021 10:31:39

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.

US3952173

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 22:16:26

Generated On: 10 Jun 2021 10:31:39

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 14:32 (24 HR)

Treatment Date and Time (derived) 29 SEP 2020 14:32

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

US3952173

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 22:16:26

Generated On: 10 Jun 2021 10:31:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	29 SEP 2020
Collection time (<i>00:00-23:59</i>)	14:08 (24 HR)
Collection date and time (derived)	29 SEP 2020 14:08

US3952173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 22:16:26

Generated On: 10 Jun 2021 10:31:39

Collection date (dd MMM yyyy)			29 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:20	29 SEP 2020 14:20
Nasopharyngeal Swab 2	No		

US3952173

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:16:26

Generated On: 10 Jun 2021 10:31:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 15:34

PC Open Date & Time

29 SEP 2020 14:52

PC Close Date & Time

29 SEP 2020 17:22

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 20:27

PC Open Date & Time

29 SEP 2020 18:17

PC Close Date & Time

30 SEP 2020 11:59

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 19:04

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 19:49

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

95.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 19:03

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °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 OCT 2020 19:11

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 19:04

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:31:39

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

95.9 °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 OCT 2020 19:01

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

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

29 SEP 2020 15:21

PC Open Date & Time

29 SEP 2020 14:52

PC Close Date & Time

29 SEP 2020 17:22

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

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

29 SEP 2020 20:27

PC Open Date & Time

29 SEP 2020 18:17

PC Close Date & Time

30 SEP 2020 11:59

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:31:39

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

30 SEP 2020 19:04

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:31:39

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

01 OCT 2020 19:50

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:31:39

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

02 OCT 2020 19:03

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:31:39

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

03 OCT 2020 19:12

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:31:39

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

04 OCT 2020 19:04

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:31:39

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

05 OCT 2020 19:02

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

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 ☐

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 15:26
PC Open Date & Time	29 SEP 2020 14:52
PC Close Date & Time	29 SEP 2020 17:22

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

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 ☐

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 20:28
PC Open Date & Time	29 SEP 2020 18:17
PC Close Date & Time	30 SEP 2020 11:59

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

46 of 1797

EAB) (1725)

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:31:39

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 19:06
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

48 of 1797

EAB) (1725)

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:31:39

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 19:51
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

50 of 1797

EAB) (1725)

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:31:39

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 19:04
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:31:39

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

52 of 1797

EAB) (1725)

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:31:39

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 19:13
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:31:39

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

54 of 1797

EAB) (1725)

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:31:39

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 19:05
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

56 of 1797

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:31:39

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 19:02
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3952173

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:16:23

Generated On: 10 Jun 2021 10:31:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952173

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:16:23

Generated On: 10 Jun 2021 10:31:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952173

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:16:23

Generated On: 10 Jun 2021 10:31:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952173

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:16:23

Generated On: 10 Jun 2021 10:31:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952173

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:16:23

Generated On: 10 Jun 2021 10:31:39

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 20 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3952173

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:16:23

Generated On: 10 Jun 2021 10:31:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952173

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:16:26

Generated On: 10 Jun 2021 10:31:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 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	VISIT2

US3952173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 22:16:26

Generated On: 10 Jun 2021 10:31:39

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 OCT 2020
Time of assessment (00:00-23:59)	10:09 (24 HR)
Vital Signs Date and Time (derived)	29 OCT 2020 10:09
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	106 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3952173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 22:16:26

Generated On: 10 Jun 2021 10:31:39

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	29 OCT 2020
Time of assessment (00:00-23:59)	11:40 (24 HR)
Vital Signs Date and Time (derived)	29 OCT 2020 11:40
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	97 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3952173

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 22:16:26

Generated On: 10 Jun 2021 10:31:39

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.

US3952173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 22:16:26

Generated On: 10 Jun 2021 10:31:39

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 10:56 (24 HR)

Treatment Date and Time (derived) 29 OCT 2020 10:56

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

What was the frequency of the study treatment dosing? ONCE

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

US3952173

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 22:16:26

Generated On: 10 Jun 2021 10:31:39

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 OCT 2020

Collection time (00:00-23:59)

10:47 (24 HR)

Collection date and time (derived)

29 OCT 2020 10:47

US3952173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 22:16:26

Generated On: 10 Jun 2021 10:31:39

Collection date (dd MMM yyyy)			29 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:41	29 OCT 2020 10:41
Nasopharyngeal Swab 2	No		

US3952173

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:16:26

Generated On: 10 Jun 2021 10:31:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

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

29 OCT 2020 11:43

PC Open Date & Time

29 OCT 2020 11:16

PC Close Date & Time

29 OCT 2020 13:46

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 95.8 °F

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

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

PC Time Stamp	29 OCT 2020 19:06
PC Open Date & Time	29 OCT 2020 14:41
PC Close Date & Time	30 OCT 2020 11:59

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.6 °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

30 OCT 2020 19:07

PC Open Date & Time

30 OCT 2020 12:00

PC Close Date & Time

31 OCT 2020 11:59

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 OCT 2020 19:02

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

95.6 °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

01 NOV 2020 19:01

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

95.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 NOV 2020 19:01

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

95.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 NOV 2020 19:00

PC Open Date & Time

03 NOV 2020 12:00

PC Close Date & Time

04 NOV 2020 11:59

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

04 NOV 2020 19:01

PC Open Date & Time

04 NOV 2020 12:00

PC Close Date & Time

05 NOV 2020 11:59

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 OCT 2020 11:44

PC Open Date & Time

29 OCT 2020 11:16

PC Close Date & Time

29 OCT 2020 13:46

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

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

29 OCT 2020 19:07

PC Open Date & Time

29 OCT 2020 14:41

PC Close Date & Time

30 OCT 2020 11:59

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:31:39

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

30 OCT 2020 19:07

PC Open Date & Time

30 OCT 2020 12:00

PC Close Date & Time

31 OCT 2020 11:59

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 OCT 2020 19:02

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 NOV 2020 19:02

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 NOV 2020 19:02

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 NOV 2020 19:00

PC Open Date & Time

03 NOV 2020 12:00

PC Close Date & Time

04 NOV 2020 11:59

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 NOV 2020 19:01

PC Open Date & Time

04 NOV 2020 12:00

PC Close Date & Time

05 NOV 2020 11:59

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

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 ☐

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

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

No ☒

Yes ☐

PC Time stamp	29 OCT 2020 11:44
PC Open Date & Time	29 OCT 2020 11:16
PC Close Date & Time	29 OCT 2020 13:46

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

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 ☐

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

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

No ☒

Yes ☐

PC Time stamp	29 OCT 2020 19:07
PC Open Date & Time	29 OCT 2020 14:41
PC Close Date & Time	30 OCT 2020 11:59

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:31:39

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 ☒

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:31:39

Yes <input type="checkbox"/>	
PC Time stamp	30 OCT 2020 19:08
PC Open Date & Time	30 OCT 2020 12:00
PC Close Date & Time	31 OCT 2020 11:59

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

94 of 1797

EAB) (1725)

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:31:39

Yes <input type="checkbox"/>	
PC Time stamp	31 OCT 2020 19:03
PC Open Date & Time	31 OCT 2020 12:00
PC Close Date & Time	01 NOV 2020 11:59

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

96 of 1797

EAB) (1725)

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:31:39

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

98 of 1797

EAB) (1725)

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:31:39

Yes <input type="checkbox"/>	
PC Time stamp	02 NOV 2020 19:02
PC Open Date & Time	02 NOV 2020 12:00
PC Close Date & Time	03 NOV 2020 11:59

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:31:39

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

100 of 1797

EAB) (1725)

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:31:39

Yes <input type="checkbox"/>	
PC Time stamp	03 NOV 2020 19:01
PC Open Date & Time	03 NOV 2020 12:00
PC Close Date & Time	04 NOV 2020 11:59

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

102 of 1797

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:31:39

Yes <input type="checkbox"/>	
PC Time stamp	04 NOV 2020 19:01
PC Open Date & Time	04 NOV 2020 12:00
PC Close Date & Time	05 NOV 2020 11:59

US3952173

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:49:02

Generated On: 10 Jun 2021 10:31:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952173

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:49:02

Generated On: 10 Jun 2021 10:31:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952173

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:16:23

Generated On: 10 Jun 2021 10:31:39

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3952173

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:16:23

Generated On: 10 Jun 2021 10:31:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952173

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:16:23

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:16:23

Generated On: 10 Jun 2021 10:31:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952173

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:16:26

Generated On: 10 Jun 2021 10:31:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 NOV 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

US3952173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 22:16:26

Generated On: 10 Jun 2021 10:31:39

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) _____

US3952173

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 22:16:26

Generated On: 10 Jun 2021 10:31:39

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.

US3952173

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 22:16:26

Generated On: 10 Jun 2021 10:31:39

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 NOV 2020

Collection time (00:00-23:59)

14:55 (24 HR)

Collection date and time (derived)

24 NOV 2020 14:55

US3952173

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:16:26

Generated On: 10 Jun 2021 10:31:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

26 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2020 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 DEC 2020 06:16:12
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 DEC 2020 09:43:00
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

17 DEC 2020 08:03:36

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

24 DEC 2020 09:17:08

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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	31 DEC 2020 08:53:19
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

07 JAN 2021 17:34:30

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 JAN 2021 09:20:17
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 JAN 2021 20:41:54

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

28 JAN 2021 08:48:04

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 FEB 2021 07:55:24

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

11 FEB 2021 12:51:35

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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 <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	18 FEB 2021 17:09:18
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

25 FEB 2021 09:49:07

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 MAR 2021 09:05:20

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

11 MAR 2021 08:35:17

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

18 MAR 2021 10:49:38

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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 MAR 2021 06:44:47

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 APR 2021 09:03:43

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 11:26:44

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 20:06:25

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

22 APR 2021 06:58:21

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

29 APR 2021 11:48:03

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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 <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"/>

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 243

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

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

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

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

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

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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 <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"/>

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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 ☐

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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 ☐

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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 ☐

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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 <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"/>

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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 ☐

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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="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"/>

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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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US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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 ☐

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 334

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

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

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

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

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

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

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 ☐

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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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US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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"/>

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 348

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

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

No ☐

Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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 ☐

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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 ☐

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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 ☐

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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 ☐

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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 ☐

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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"/>

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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 ☐

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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"/>

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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 ☐

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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 ☐

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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 ☐

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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°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 ☐

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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°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 ☐

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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 <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"/>

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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 ☐

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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 ☐

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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 ☐

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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 ☐

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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 ☐

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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 ☐

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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 ☐

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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"/>

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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"/>

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 642

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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 ☐

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 663

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

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

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

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

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

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

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

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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"/>

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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 ☐

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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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US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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 ☐

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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 ☐

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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="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"/>

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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="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"/>

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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"/>

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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
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Patient Cloud Close Date & Time	17 OCT 2022 23:59
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US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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 ☐

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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
Patient Cloud Close Date & Time	24 OCT 2022 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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 ☐

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 OCT 2022 00:01
Patient Cloud Close Date & Time	31 OCT 2022 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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 ☐

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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 ☐

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

17 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2022 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

24 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2022 23:59

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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"/>

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 10:31:39

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		04 MAR 2021 09:06:32

US3952173

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:49:02

Generated On: 10 Jun 2021 10:31:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952173

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:49:02

Generated On: 10 Jun 2021 10:31:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952173

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 20:31:56

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 20:31:56

Generated On: 10 Jun 2021 10:31:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952173

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 20:31:56

Generated On: 10 Jun 2021 10:31:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952173

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 20:31:56

Generated On: 10 Jun 2021 10:31:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952173

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 20:31:56

Generated On: 10 Jun 2021 10:31:39

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3952173

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 20:31:56

Generated On: 10 Jun 2021 10:31:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952173

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:31:39

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3952173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:31:39

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3952173

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:31:39

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.

US3952173

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:31:39

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00-23:59</i>)	<hr/>
Collection date and time (derived)	<hr/>

US3952173

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:31:39

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3952173

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:31:39

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"/>

US3952173

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 10:31:39

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3952173

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

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 20:31:55

Generated On: 10 Jun 2021 10:31:39

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

Visit date (dd MMM yyyy)	23 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3952173

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

Form: Unblinding

Data signed: (b) (4) 08 Apr 2021 20:31:55

Generated On: 10 Jun 2021 10:31:39

Date of updated informed consent (<i>dd MMM yyyy</i>)	23 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	23 FEB 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3952173

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 08 Apr 2021 20:31:55

Generated On: 10 Jun 2021 10:31:39

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

US3952173

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Apr 2021 20:31:55

Generated On: 10 Jun 2021 10:31:39

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	09 MAR 2021
Time of assessment (00:00-23:59)	12:17 (24 HR)
Vital Signs Date and Time (derived)	09 MAR 2021 12:17
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	120 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	95 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3952173

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Apr 2021 20:31:55

Generated On: 10 Jun 2021 10:31:39

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	09 MAR 2021
Time of assessment (00:00-23:59)	13:34 (24 HR)
Vital Signs Date and Time (derived)	09 MAR 2021 13:34
Temperature (xxx.x)	100.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	121 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3952173

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

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 20:31:55

Generated On: 10 Jun 2021 10:31:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 MAR 2021

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

US3952173

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

Form: Exposure

Data signed: (b) (4) 08 Apr 2021 20:31:55

Generated On: 10 Jun 2021 10:31:39

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 09 MAR 2021

What was the treatment time? (00:00-23:59) 12:57 (24 HR)

Treatment Date and Time (derived) 09 MAR 2021 12:57

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

US3952173

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 20:31:55

Generated On: 10 Jun 2021 10:31:39

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 FEB 2021

Collection time (00:00-23:59)

12:27 (24 HR)

Collection date and time (derived)

23 FEB 2021 12:27

US3952173

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 08 Apr 2021 20:31:55

Generated On: 10 Jun 2021 10:31:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 FEB 2021
Collection time (00:00 - 23:59)	12:30
Collection Date and Time (derived)	23 FEB 2021 12:30

US3952173

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

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 20:31:55

Generated On: 10 Jun 2021 10:31:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952173

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 20:31:56

Generated On: 10 Jun 2021 10:31:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952173

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 20:31:56

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:31:39

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3952173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	

US3952173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	

US3952173

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:31:39

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.

US3952173

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:31:39

Was study treatment given? Yes ☐
No ☐

If No, reason not given

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

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

What was the study treatment? (Unblinded) _____

What was the treatment date? (dd MMM yyyy) _____

What was the treatment time? (00:00-23:59) _____

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3952173

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:31:39

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3952173

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 08 Apr 2021 19:13:14

Generated On: 10 Jun 2021 10:31:39

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3952173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:31:39

AEID	USA-US215-2021-MRNA-1273-P30 1000007
Adverse event	(L) EYE RETINAL ARTERY OCCLUSION
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)	24 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)	31 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)	29 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	31 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input checked="" type="radio"/>
Number of Days in ICU	
PRODUCTION RELEASE (v12.003 EAB) (1725)	340 of 1797

US3952173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:31:39

SUBJECT ADMITTED TO
HOSPITAL ON 29 MAR2021
WITH BLURRED (L) VISION.
DIAGNOSED WITH (L) RETINAL
ARTERY OCCLUSION. PMH -
HYPERTENSION
DISCHARGED FROM HOSPITAL
ON 31MAR2021ON
MEDICATION THAT SUBJECT
WILL PROVIDE DETAILS ON.
MEDICAL RECORDS HAVE
BEEN REQUESTED AND
UPDATE WILL BE PROVIDED
UPON RECEIPT AND REVIEW.

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

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

AEID	USA-US215-2021-MRNA-1273-P30 1000008
Adverse event	OLIGOARTHRITIS SECONDARY TO PSEUDOGOUT FLARE
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)	08 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input 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 APR 2021
Hospital Discharge Date (dd MMM yyyy)	12 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
PRODUCTION RELEASE (v12.003 EAB) (1725)	343 of 1797

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

SUBJECT ADMITTED TO
HOSPITAL WITH (L) KNEE
SWELLING ON 09APR2021.
STATES THAT SYMPTOMS
BEGAN 08APR2021 EVENING.
COULD NOT BEAR WEIGHT
AND WAS ADMITTED TO
HOSPITAL. HAS HAD KNEE
DRAINED. CURRENTLY
REPORTS THAT (R) KNEE IS
NOW SWOLLEN. SUBJECT
UNCERTAIN OF DIAGNOSIS.
FURTHER INFORMATION WILL
BE PROVIDED UPON RECEIPT
OF MEDICAL RECORDS UPON
DISCHARGE.

MEDICAL RECORDS RECEIVED
AND REVIEWED.
ADMIT DATE 09APR2021
SYMPTOM ONSET 08APR2021
DISCHARGE DATE 12APR2021
CLARIFICATION - SUBJECT
ADMITTED WITH (R) KNEE
SWELLING (NOT LEFT AS HE
DESCRIBED). IN HOSPITAL
DEVELOPED (L) KNEE
SWELLING AS WELL.

SUBJECT WITH HX OF
PSEUDOGOUT, WAS ADMITTED
FOR CONCERNS OF SEPTIC
ARTHRITIS VS PSEUDOGOUT
FLARE GIVEN HIS (R) KNEE
SWELLING AND PAIN FOR ONE
DAY. DURING HIS
HOSPITALIZATION, HIS (R)

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

KNEE SWELLING AND PAIN
DECREASED SIGNIFICANTLY
AFTER RECEIVING
COLCHICINE, VANCOMYCIN,
CEFTRIAXONE AND
IBUPROFEN. HIS HOSPITAL
COURSE WAS COMPLICATED
BY THE DEVELOPMENT OF L
KNEE PAIN AND SWELLING ON
11APR2021 THAT RESOLVED ON
12APR2021. GIVEN HIS
HISTORY OF PSEUDOGOUT,
INVOLVEMENT OF MORE THAN
ONE JOINT, THE LACK OF
GROWTH ON BLOOD AND
SYNOVIAL FLUID CULTURES
FOR 3 DAYS, AND THE LACK OF
ORGANISMS REPORTED IN
SYNOVIAL FLUID, THIS WAS
MOST LIKELY A PSEUDOGOUT
FLARE THAT HAS RESOLVED.

RHEUMATOLOGY AND ORTHO
CONSULTS DURING HIS
HOSPITAL STAY.

PROCEDURES -
ARTHROCENTESIS WITH SBC
77, 93% PMNS, NO ORGANISMS.
RECEIVED VANCOMYCIN
X2DYS AND CEFTRIAXONE X1
DY FOR POSSIBLE SEPTIC
ARTHRITIS. MEDS STOPPED
WHEN UNLIKELY DX OF SEPTIC
ARTHRITIS.
XRAY OF (R) KNEE - 09APR2021
- MODERATE

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

<hr/>	
SIZED SUPRAPATELLAR JOINT EFFUSION WITH ADVANCED OSTEOARTHRITIS CHEST XRAY - 09APR2021 - OA (B) SHOULDERS WITH MILD CARDIOMEGALY CTA - CHEST - MILD EMPHYSEMA, STABLE NODULES	
BOTH (R) AND (L) KNEE SWELLING/PAIN RESOLVED WITH COLCHICINE AND IBUPROFEN. PATIENT DISCHARGED HOME ON 12APR2021 WITH PLAN TO CONTINUE COLCHICINE.	
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
<hr/>	

US3952173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 08 Apr 2021 20:31:55

Generated On: 10 Jun 2021 10:31:39

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

Yes ☒

No ☐

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

US3952173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 20:31:55

Generated On: 10 Jun 2021 10:31:39

Name of Medication AMLODIPINE BESYLATE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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 ☐

PRODUCTION RELEASE (v12.003

349 of 1797

EAB) (1725)

US3952173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 20:31:55

Generated On: 10 Jun 2021 10:31:39

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3952173

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 20:31:55

Generated On: 10 Jun 2021 10:31:39

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3952173

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:31:39

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

US3952173

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:31:39

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 ☐

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 09 Apr 2021 20:18:47

Generated On: 10 Jun 2021 10:31:39

SAEID	USA-US215-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIMI
Investigator's Last Name	VAN DER LEDEN
Site Address: Street	15201 SHADY GROVE DR
Site Address: City	ROCKVILLE
Site Address: State	
Site Address: Postal Code	20850
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 09 Apr 2021 20:18:47

Generated On: 10 Jun 2021 10:31:39

SAEID	USA-US215-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIMI
Investigator's Last Name	VAN DER LEDEN
Site Address: Street	15201 SHADY GROVE DR
Site Address: City	ROCKVILLE
Site Address: State	
Site Address: Postal Code	20850
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	08/APR/2021 06:20
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

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 09 Apr 2021 20:18:47

Generated On: 10 Jun 2021 10:31:39

SAEID	USA-US215-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIMI
Investigator's Last Name	VAN DER LEDEN
Site Address: Street	15201 SHADY GROVE DR
Site Address: City	ROCKVILLE
Site Address: State	
Site Address: Postal Code	20850
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	09/APR/2021 08:18
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 22 Apr 2021 16:05:48

Generated On: 10 Jun 2021 10:31:39

SAEID	USA-US215-2021-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	MIMI
Investigator's Last Name	VAN DER LEDEN
Site Address: Street	15201 SHADY GROVE DR
Site Address: City	ROCKVILLE
Site Address: State	
Site Address: Postal Code	20850
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 22 Apr 2021 16:05:48

Generated On: 10 Jun 2021 10:31:39

SAEID	USA-US215-2021-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	MIMI
Investigator's Last Name	VAN DER LEDEN
Site Address: Street	15201 SHADY GROVE DR
Site Address: City	ROCKVILLE
Site Address: State	
Site Address: Postal Code	20850
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	13/APR/2021 12:27
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Data signed: (b) (4) 22 Apr 2021 16:05:48

Generated On: 10 Jun 2021 10:31:39

SAEID	USA-US215-2021-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	MIMI
Investigator's Last Name	VAN DER LEDEN
Site Address: Street	15201 SHADY GROVE DR
Site Address: City	ROCKVILLE
Site Address: State	
Site Address: Postal Code	20850
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	20/APR/2021 13:34
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

Audit

US3952173 (Prod: Synexus - Optimal Research - Rockville)

US3952173

Form: Participant Creation

Generated On: 10 Jun 2021 10:31:39

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered 'US3952173'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	29 Sep 2020 17:12:48

US3952173

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:31:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:33:10

US3952173

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '29 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Sep 2020 17:12:49

US3952173

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'Clinic (Clinic)'	Nick Bart (b) (4)	05 Oct 2020 14:33:10

US3952173

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:31:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User entered 'SCRN'	System	05 Oct 2020 14:33:10

US3952173

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:31:39

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:23
User entered (b) (6) 1956'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Sep 2020 17:12:50

US3952173

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:31:39

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:23
User entered '64'	Nick Bart (b) (4)	05 Oct 2020 14:38:34

US3952173

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:31:39

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User entered 'YEARS'	System	05 Oct 2020 14:38:34

US3952173

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:31:39

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User entered '64'	System	29 Sep 2020 18:59:08

US3952173

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:31:39

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:23
User entered 'Male (M)'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:38:34

US3952173

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:31:39

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:23
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:38:34

US3952173

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:31:39

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:23
User entered '0'	Nick Bart (b) (4)	05 Oct 2020 14:38:34

US3952173

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:31:39

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:23
User entered 'I'	Nick Bart (b) (4)	05 Oct 2020 14:38:34

US3952173

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:31:39

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:23
User entered '0'	Nick Bart (b) (4)	05 Oct 2020 14:38:34

US3952173

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:31:39

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:23
User entered '0'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:38:34

US3952173

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:31:39

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:23
User entered '0'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:38:34

US3952173

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:31:39

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:23
User entered '0'	Nick Bart (b) (4)	05 Oct 2020 14:38:34

US3952173

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:31:39

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:23
User entered empty.	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:38:34

US3952173

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:31:39

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:23
User entered '0'	Nick Bart (b) (4)	05 Oct 2020 14:38:34

US3952173

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:31:39

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:23
User entered '0'	Nick Bart (b) (4)	05 Oct 2020 14:38:34

US3952173

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:31:39

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '29 Sep 2020'	Brianne Okunji (b) (4)	29 Sep 2020 18:59:08

US3952173

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User entered 'Sep 2020'	System	29 Sep 2020 18:59:08

US3952173

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User entered '2020'	System	29 Sep 2020 18:59:08

US3952173

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:31:39

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'Amendment 3 (3)'	Brianne Okunji (b) (4)	29 Sep 2020 18:59:08

US3952173

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'Yes (Y)'	Brianne Okunji (b) (4)	29 Sep 2020 18:59:08

US3952173

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:31:39

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered empty.	Brianne Okunji (b) (4)	29 Sep 2020 18:59:08

US3952173

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:31:39

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered empty.	Brianne Okunji (b) (4)	29 Sep 2020 18:59:08

US3952173

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:31:39

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'No (N)'	Brianne Okunji (b) (4)	29 Sep 2020 18:59:08

US3952173

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:31:39

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Sep 2020 17:12:49

US3952173

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:31:39

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User entered 'I'	System	29 Sep 2020 18:59:25

US3952173

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'Yes (Y)'	Brianne Okunji (b) (4)	29 Sep 2020 18:59:25

US3952173

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:31:39

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:34:12

US3952173

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:31:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Hepatitis viral infections, PT: Hepatitis B, LLT: Hepatitis B - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 14:35:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 14:35:30
Data point term sent to Coder	System	05 Oct 2020 14:34:38
User entered 'hepatitis b'	Nick Bart (b) (4)	05 Oct 2020 14:34:27

US3952173

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'un UNK 1998'	Nick Bart (b) (4)	05 Oct 2020 14:34:27

US3952173

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:31:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '0'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:34:27

US3952173

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:31:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:34:27

US3952173

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:31:39

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered empty.	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:34:27

US3952173

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:31:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '0'	Nick Bart (b) (4)	05 Oct 2020 14:34:27

US3952173

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User entered 'Jan 1998'	System	05 Oct 2020 14:34:27

US3952173

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User entered '1998'	System	05 Oct 2020 14:34:27

US3952173

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User entered empty.	System	05 Oct 2020 14:34:27

US3952173

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User entered empty.	System	05 Oct 2020 14:34:27

US3952173

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:31:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Miscellaneous and site unspecified neoplasms malignant and unspecified, HLT: Neoplasms malignant site unspecified NEC, PT: Cancer in remission, LLT: Cancer in remission - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	05 Oct 2020 16:15:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:15:18
Data point term sent to Coder	System	05 Oct 2020 14:35:41
User entered 'prostate cancer [in remission]'	Nick Bart (b) (4)	05 Oct 2020 14:35:01

US3952173

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'un UNK 2013'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:35:01

US3952173

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:31:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '0'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:35:01

US3952173

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:31:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:35:01

US3952173

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:31:39

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'un UNK 2013'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:35:01

US3952173

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:31:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '0'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:35:01

US3952173

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User entered 'Jan 2013'	System	05 Oct 2020 14:35:01

US3952173

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User entered '2013'	System	05 Oct 2020 14:35:01

US3952173

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User entered 'Jan 2013'	System	05 Oct 2020 14:35:01

US3952173

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User entered '2013'	System	05 Oct 2020 14:35:01

US3952173

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:31:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Limb therapeutic procedures, PT: Limb operation, LLT: Leg operation - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	05 Oct 2020 14:36:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 14:36:22
Data point term sent to Coder	System	05 Oct 2020 14:35:42
User entered 'left leg surgery'	Nick Bart (b) (4)	05 Oct 2020 14:35:25

US3952173

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'un Jun 2000'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:35:25

US3952173

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:31:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '0'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:35:25

US3952173

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:31:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:35:25

US3952173

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:31:39

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'un Sep 2000'	Nick Bart (b) (4)	05 Oct 2020 14:35:25

US3952173

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:31:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '0'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:35:25

US3952173

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User entered 'Jun 2000'	System	05 Oct 2020 14:35:25

US3952173

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User entered '2000'	System	05 Oct 2020 14:35:25

US3952173

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User entered 'Sep 2000'	System	05 Oct 2020 14:35:25

US3952173

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User entered '2000'	System	05 Oct 2020 14:35:25

US3952173

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:31:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	05 Oct 2020 14:37:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 14:37:14
Data point term sent to Coder	System	05 Oct 2020 14:36:47
User entered 'hypertension'	Nick Bart (b) (4)	05 Oct 2020 14:36:40

US3952173

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'un UNK 2013'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:36:40

US3952173

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:31:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '0'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:36:40

US3952173

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:31:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:36:40

US3952173

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:31:39

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered empty.	Nick Bart (b) (4)	05 Oct 2020 14:36:40

US3952173

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:31:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '0'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:36:40

US3952173

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User entered 'Jan 2013'	System	05 Oct 2020 14:36:40

US3952173

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User entered '2013'	System	05 Oct 2020 14:36:40

US3952173

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User entered empty.	System	05 Oct 2020 14:36:40

US3952173

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User entered empty.	System	05 Oct 2020 14:36:40

US3952173

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:31:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Visual disorders NEC, PT: Vision blurred, LLT: Blurred vision - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	05 Oct 2020 16:19:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:19:21
Data point term sent to Coder	System	05 Oct 2020 14:38:49
User entered 'right eye blurred vision'	Nick Bart (b) (4)	05 Oct 2020 14:38:04

US3952173

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'un UNK 2018'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:38:04

US3952173

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:31:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '0'	Nick Bart (b) (4)	05 Oct 2020 14:38:04

US3952173

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:31:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:38:04

US3952173

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:31:39

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered empty.	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:38:04

US3952173

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:31:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '0'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:38:04

US3952173

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User entered 'Jan 2018'	System	05 Oct 2020 14:38:04

US3952173

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User entered '2018'	System	05 Oct 2020 14:38:04

US3952173

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User entered empty.	System	05 Oct 2020 14:38:04

US3952173

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User entered empty.	System	05 Oct 2020 14:38:04

US3952173

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:31:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:33:47

US3952173

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:31:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '29 Sep 2020'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:33:47

US3952173

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '12:43'	Nick Bart (b) (4)	05 Oct 2020 14:33:47

US3952173

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User entered '29 Sep 2020 12:43'	System	05 Oct 2020 14:33:47

US3952173

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '69.0' in	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:33:47
DataPoint set to visible.	System	29 Sep 2020 18:59:25

US3952173

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '189.0' lb	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:33:47
DataPoint set to visible.	System	29 Sep 2020 18:59:25

US3952173

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:31:39

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User entered '27.96878'	System	05 Oct 2020 14:33:47
DataPoint set to visible.	System	29 Sep 2020 18:59:25

US3952173

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:31:39

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User entered 'kg/m2'	System	05 Oct 2020 14:33:47
DataPoint set to visible.	System	29 Sep 2020 18:59:25

US3952173

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:33:47

US3952173

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:31:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered empty.	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:33:47

US3952173

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:31:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered empty.	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:33:47

US3952173

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:31:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:33:47

US3952173

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:31:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User entered 'bpm'	System	05 Oct 2020 14:33:47

US3952173

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:33:47

US3952173

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:31:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User entered 'breaths/min'	System	05 Oct 2020 14:33:47

US3952173

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:33:47

US3952173

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:31:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User entered 'mmHg'	System	05 Oct 2020 14:33:47

US3952173

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:33:47

US3952173

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:31:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User entered 'mmHg'	System	05 Oct 2020 14:33:47

US3952173

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:31:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 18:33:49

US3952173

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:31:39

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 18:33:49

US3952173

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:31:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:38:15

US3952173

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:31:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '29 Sep 2020'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:38:15

US3952173

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:39:36

US3952173

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:39:36

US3952173

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:31:39

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)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'No (N)'	Nick Bart (b) (4)	05 Oct 2020 14:39:36

US3952173

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:31:39

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)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'No (N)'	Nick Bart (b) (4)	05 Oct 2020 14:39:36

US3952173

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:39:36

US3952173

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:31:39

[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)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'No (N)'	Nick Bart (b) (4)	05 Oct 2020 14:39:36

US3952173

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:31:39

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)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'No (N)'	Nick Bart (b) (4)	05 Oct 2020 14:39:36

US3952173

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:31:39

[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)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'No (N)'	Nick Bart (b) (4)	05 Oct 2020 14:39:36

US3952173

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:31:39

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)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:39:36

US3952173

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:31:39

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)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'No (N)'	Nick Bart (b) (4)	05 Oct 2020 14:39:36

US3952173

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:31:39

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)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'No (N)'	Nick Bart (b) (4)	05 Oct 2020 14:39:36

US3952173

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:31:39

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'Yes (Y)'	Nick Bart (b) (4)	05 Oct 2020 14:39:36

US3952173

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:31:39

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'disabled, retired veteran. grocery shops twice weekly.'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:39:36

US3952173

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:31:39

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '0'	Nick Bart (b) (4)	05 Oct 2020 14:39:36

US3952173

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:31:39

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '0'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:39:36

US3952173

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:31:39

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)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '0'	Nick Bart (b) (4)	05 Oct 2020 14:39:36

US3952173

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:31:39

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)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '0'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:39:36

US3952173

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:31:39

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)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'I'	Nick Bart (b) (4)	05 Oct 2020 14:39:36

US3952173

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:31:39

Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '0'	Nick Bart (b) (4)	05 Oct 2020 14:39:36

US3952173

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:31:39

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '0'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:39:36

US3952173

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:31:39

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:49
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered empty.	Nick Bart (b) (4)	05 Oct 2020 14:39:36

US3952173

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:31:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:17:19

US3952173

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '29 Sep 2020'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:17:19

US3952173

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:31:39

[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 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'Clinic (Clinic)'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:17:19

US3952173

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:31:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User entered 'VISIT1'	System	05 Oct 2020 14:17:19

US3952173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '29 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Sep 2020 17:52:45

US3952173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '116016'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Sep 2020 17:52:45

US3952173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Sep 2020 17:52:45

US3952173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:31:39

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 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:17:38

US3952173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:31:39

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 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'No (N)'	Nick Bart (b) (4)	05 Oct 2020 14:17:38

US3952173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:17:38

US3952173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:31:39

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:17:38

US3952173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:31:39

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:17:38

US3952173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:17:38
DataPoint set to visible.	System	29 Sep 2020 18:59:08

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:31:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:18:37

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:31:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:18:37

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:31:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:18:37

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:31:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:18:37

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User accepted default value 'Pre-Dose (PREDOSE)'	Nick Bart (b) (4)	05 Oct 2020 14:18:37

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:18:37

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '29 Sep 2020'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:18:37

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '12:43'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:18:37

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User entered '29 Sep 2020 12:43'	System	05 Oct 2020 14:18:37

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '36.8' C	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:18:37

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'Oral (Oral)'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:18:37

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered empty.	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:18:37

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '95'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:18:37

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User entered 'bpm'	System	05 Oct 2020 14:18:37

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '16'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:18:37

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User entered 'breaths/min'	System	05 Oct 2020 14:18:37

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '127'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:18:37

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User entered 'mmHg'	System	05 Oct 2020 14:18:37

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '79'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:18:37

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User entered 'mmHg'	System	05 Oct 2020 14:18:37

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:31:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:18:37

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:31:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:18:37

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User accepted default value 'Post-Dose (POSTDOSE)'	Nick Bart (b) (4)	05 Oct 2020 14:18:37

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:18:37

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '29 Sep 2020'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:18:37

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '15:30'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:18:37

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User entered '29 Sep 2020 15:30'	System	05 Oct 2020 14:18:37

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '36.6' C	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:18:37

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'Oral (Oral)'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:18:37

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered empty.	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:18:37

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '89'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:18:37

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User entered 'bpm'	System	05 Oct 2020 14:18:37

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '12'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:18:37

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User entered 'breaths/min'	System	05 Oct 2020 14:18:37

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '135'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:18:37

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User entered 'mmHg'	System	05 Oct 2020 14:18:37

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '81'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:18:37

US3952173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User entered 'mmHg'	System	05 Oct 2020 14:18:37

US3952173

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:31:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:17:07

US3952173

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:31:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered empty.	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:17:07

US3952173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:31:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'Yes (Y)'	(b) (4) Brianne Okunji (b) (4) (b) (4)	29 Sep 2020 19:01:05

US3952173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:31:39

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered empty.	(b) (4) Brianne Okunji (b) (4) (b) (4)	29 Sep 2020 19:01:05

US3952173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:31:39

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 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered empty.	Brianne Okunji (b) (4)	29 Sep 2020 19:01:05

US3952173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:31:39

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User entered 'MRNA-1273 OR PLACEBO'	System	29 Sep 2020 19:01:05

US3952173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:31:39

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '29 Sep 2020'	(b) (4) Brianne Okunji (b) (4) (b) (4)	29 Sep 2020 19:01:05

US3952173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:31:39

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '14:32'	(b) (4) Brianne Okunji (b) (4) (b) (4)	29 Sep 2020 19:01:05

US3952173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:31:39

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User entered '29 Sep 2020 14:32'	System	29 Sep 2020 19:01:05

US3952173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:31:39

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'Left Arm (LEFT ARM)'	(b) (4) Brianne Okunji (b) (4) (b) (4)	29 Sep 2020 19:01:05

US3952173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:31:39

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User entered 'ONCE'	System	29 Sep 2020 19:01:05

US3952173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:31:39

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User entered 'INTRAMUSCULAR'	System	29 Sep 2020 19:01:05

US3952173

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:31:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:32:41

US3952173

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:31:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '29 Sep 2020'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:32:41

US3952173

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:31:39

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '14:08'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:32:41

US3952173

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:31:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User entered '29 Sep 2020 14:08'	System	05 Oct 2020 14:32:41

US3952173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:31:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '29 Sep 2020'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:32:55

US3952173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:31:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Nick Bart (b) (4)	05 Oct 2020 14:32:55

US3952173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:31:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:32:55

US3952173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:31:39

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '14:20'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:32:55

US3952173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:31:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User entered '29 Sep 2020 14:20'	System	05 Oct 2020 14:32:55

US3952173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:31:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Nick Bart (b) (4)	05 Oct 2020 14:32:55

US3952173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:31:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:32:55

US3952173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:31:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered empty.	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:32:55

US3952173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:31:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User entered empty.	System	05 Oct 2020 14:32:55

US3952173

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:31:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:17:10

US3952173

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:31:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User entered '1'	System	05 Oct 2020 14:17:10

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Sep 2020 19:01:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-29T15:34:00', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '163aab41-07c4-46d0-9f6b-79248e7b9f8e'	System	29 Sep 2020 19:34:49
User entered 'Yes (Y)'	System	29 Sep 2020 19:34:49

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-29T15:34:34', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '163aab41-07c4-46d0-9f6b-79248e7b9f8e'	System	29 Sep 2020 19:34:49
User entered '97.9'	System	29 Sep 2020 19:34:49

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-29T15:34:41', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '163aab41-07c4-46d0-9f6b-79248e7b9f8e'	System	29 Sep 2020 19:34:49
User entered 'No (N)'	System	29 Sep 2020 19:34:49

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-29T15:34:48', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '163aab41-07c4-46d0-9f6b-79248e7b9f8e'	System	29 Sep 2020 19:34:49
User entered '29 Sep 2020 15:34'	System	29 Sep 2020 19:34:49

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '29 Sep 2020 14:52'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '29 Sep 2020 17:22'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Sep 2020 19:01:05
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-29T20:24:36', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '30e75347-bdfc-4506-afb3-9910b6860c53'	System	30 Sep 2020 00:27:00
User entered 'Yes (Y)'	System	30 Sep 2020 00:27:00

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-29T20:26:19', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '30e75347-bdfc-4506-afb3-9910b6860c53'	System	30 Sep 2020 00:27:00
User entered '97.3'	System	30 Sep 2020 00:27:00

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-29T20:26:28', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '30e75347-bdfc-4506-afb3-9910b6860c53'	System	30 Sep 2020 00:27:00
User entered 'No (N)'	System	30 Sep 2020 00:27:00

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-29T20:27:00', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '30e75347-bdfc-4506-afb3-9910b6860c53'	System	30 Sep 2020 00:27:00
User entered '29 Sep 2020 20:27'	System	30 Sep 2020 00:27:00

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '29 Sep 2020 18:17'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Sep 2020 19:01:05
User entered 'Day 2'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:31:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-30T19:03:09', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'aaf15f81-0ee4-4217-9d97-b7ae5fd598dd'	System	30 Sep 2020 23:04:09
User entered 'Yes (Y)'	System	30 Sep 2020 23:04:09

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:31:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-30T19:03:42', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'aaf15f81-0ee4-4217-9d97-b7ae5fd598dd'	System	30 Sep 2020 23:04:09
User entered '96.8'	System	30 Sep 2020 23:04:09

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-30T19:03:50', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'aaf15f81-0ee4-4217-9d97-b7ae5fd598dd'	System	30 Sep 2020 23:04:09
User entered 'No (N)'	System	30 Sep 2020 23:04:09

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:31:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-30T19:04:05', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'aaf15f81-0ee4-4217-9d97-b7ae5fd598dd'	System	30 Sep 2020 23:04:09
User entered '30 Sep 2020 19:04'	System	30 Sep 2020 23:04:09

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Sep 2020 19:01:05
User entered 'Day 3'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:31:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-01T19:48:40', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '88905be5-3c9c-48a2-830c-b66de7d613b3'	System	01 Oct 2020 23:49:24
User entered 'Yes (Y)'	System	01 Oct 2020 23:49:24

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:31:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-01T19:49:05', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '88905be5-3c9c-48a2-830c-b66de7d613b3'	System	01 Oct 2020 23:49:24
User entered '96.8'	System	01 Oct 2020 23:49:24

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-01T19:49:14', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '88905be5-3c9c-48a2-830c-b66de7d613b3'	System	01 Oct 2020 23:49:24
User entered 'No (N)'	System	01 Oct 2020 23:49:24

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:31:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-01T19:49:22', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '88905be5-3c9c-48a2-830c-b66de7d613b3'	System	01 Oct 2020 23:49:24
User entered '01 Oct 2020 19:49'	System	01 Oct 2020 23:49:24

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Sep 2020 19:01:05
User entered 'Day 4'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:31:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-02T19:02:19', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '567489aa-8679-40d3-a159-39e32056effc'	System	02 Oct 2020 23:03:41
User entered 'Yes (Y)'	System	02 Oct 2020 23:03:41

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:31:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-02T19:02:47', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '567489aa-8679-40d3-a159-39e32056effc'	System	02 Oct 2020 23:03:41
User entered '95.1'	System	02 Oct 2020 23:03:41

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-02T19:02:53', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '567489aa-8679-40d3-a159-39e32056effc'	System	02 Oct 2020 23:03:41
User entered 'No (N)'	System	02 Oct 2020 23:03:41

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:31:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-02T19:03:15', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '567489aa-8679-40d3-a159-39e32056effc'	System	02 Oct 2020 23:03:41
User entered '02 Oct 2020 19:03'	System	02 Oct 2020 23:03:41

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Sep 2020 19:01:05
User entered 'Day 5'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:31:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-03T19:10:44', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'dcd60c23-4e66-49ed-ab9d-6fee38d8b886'	System	03 Oct 2020 23:11:26
User entered 'Yes (Y)'	System	03 Oct 2020 23:11:26

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:31:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-03T19:11:02', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'dcd60c23-4e66-49ed-ab9d-6fee38d8b886'	System	03 Oct 2020 23:11:26
User entered '96.9'	System	03 Oct 2020 23:11:26

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-03T19:11:10', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'dcd60c23-4e66-49ed-ab9d-6fee38d8b886'	System	03 Oct 2020 23:11:26
User entered 'No (N)'	System	03 Oct 2020 23:11:26

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:31:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-03T19:11:24', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'dcd60c23-4e66-49ed-ab9d-6fee38d8b886'	System	03 Oct 2020 23:11:26
User entered '03 Oct 2020 19:11'	System	03 Oct 2020 23:11:26

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Sep 2020 19:01:05
User entered 'Day 6'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:31:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-04T19:03:26', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '1d29e99e-867e-4441-9372-ad3c48ae9a6f'	System	04 Oct 2020 23:04:10
User entered 'Yes (Y)'	System	04 Oct 2020 23:04:10

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:31:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-04T19:03:45', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '1d29e99e-867e-4441-9372-ad3c48ae9a6f'	System	04 Oct 2020 23:04:10
User entered '96.1'	System	04 Oct 2020 23:04:10

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-04T19:03:53', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '1d29e99e-867e-4441-9372-ad3c48ae9a6f'	System	04 Oct 2020 23:04:10
User entered 'No (N)'	System	04 Oct 2020 23:04:10

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:31:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-04T19:04:08', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '1d29e99e-867e-4441-9372-ad3c48ae9a6f'	System	04 Oct 2020 23:04:10
User entered '04 Oct 2020 19:04'	System	04 Oct 2020 23:04:10

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Sep 2020 19:01:05
User entered 'Day 7'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:31:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-05T19:00:48', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '235683d2-2dfe-4d6e-9fe7-605b6f4ba533'	System	05 Oct 2020 23:01:29
User entered 'Yes (Y)'	System	05 Oct 2020 23:01:29

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:31:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-05T19:01:03', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '235683d2-2dfe-4d6e-9fe7-605b6f4ba533'	System	05 Oct 2020 23:01:29
User entered '95.9'	System	05 Oct 2020 23:01:29

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-05T19:01:15', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '235683d2-2dfe-4d6e-9fe7-605b6f4ba533'	System	05 Oct 2020 23:01:29
User entered 'No (N)'	System	05 Oct 2020 23:01:29

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:31:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-05T19:01:27', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '235683d2-2dfe-4d6e-9fe7-605b6f4ba533'	System	05 Oct 2020 23:01:29
User entered '05 Oct 2020 19:01'	System	05 Oct 2020 23:01:29

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Sep 2020 19:01:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-29T15:20:28', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '0e9f7409-854f-4083-ac9a-2ecd33436485'	System	29 Sep 2020 19:21:19
User entered 'None (1)'	System	29 Sep 2020 19:21:19

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-29T15:20:41', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '0e9f7409-854f-4083-ac9a-2ecd33436485'	System	29 Sep 2020 19:21:19
User entered 'No (N)'	System	29 Sep 2020 19:21:19

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-29T15:20:48', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '0e9f7409-854f-4083-ac9a-2ecd33436485'	System	29 Sep 2020 19:21:19
User entered 'No (N)'	System	29 Sep 2020 19:21:19

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-29T15:20:56', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '0e9f7409-854f-4083-ac9a-2ecd33436485'	System	29 Sep 2020 19:21:19
User entered 'None (1)'	System	29 Sep 2020 19:21:19

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-29T15:21:17', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '0e9f7409-854f-4083-ac9a-2ecd33436485'	System	29 Sep 2020 19:21:19
User entered '29 Sep 2020 15:21'	System	29 Sep 2020 19:21:19

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '29 Sep 2020 14:52'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '29 Sep 2020 17:22'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Sep 2020 19:01:05
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-29T20:27:18', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'cf47e310-18c6-4510-b656-9d1c30f5629d'	System	30 Sep 2020 00:27:41
User entered 'None (1)'	System	30 Sep 2020 00:27:41

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-29T20:27:23', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'cf47e310-18c6-4510-b656-9d1c30f5629d'	System	30 Sep 2020 00:27:41
User entered 'No (N)'	System	30 Sep 2020 00:27:41

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-29T20:27:28', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'cf47e310-18c6-4510-b656-9d1c30f5629d'	System	30 Sep 2020 00:27:41
User entered 'No (N)'	System	30 Sep 2020 00:27:41

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-29T20:27:35', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'cf47e310-18c6-4510-b656-9d1c30f5629d'	System	30 Sep 2020 00:27:41
User entered 'None (1)'	System	30 Sep 2020 00:27:41

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-29T20:27:40', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'cf47e310-18c6-4510-b656-9d1c30f5629d'	System	30 Sep 2020 00:27:41
User entered '29 Sep 2020 20:27'	System	30 Sep 2020 00:27:41

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '29 Sep 2020 18:17'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Sep 2020 19:01:05
User entered 'Day 2'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-30T19:04:19', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'c3d26590-1ab9-46a2-b8c2-c20ef0ea4648'	System	30 Sep 2020 23:04:59
User entered 'None (1)'	System	30 Sep 2020 23:04:59

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:31:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-30T19:04:26', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'c3d26590-1ab9-46a2-b8c2-c20ef0ea4648'	System	30 Sep 2020 23:04:59
User entered 'No (N)'	System	30 Sep 2020 23:04:59

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-30T19:04:31', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'c3d26590-1ab9-46a2-b8c2-c20ef0ea4648'	System	30 Sep 2020 23:04:59
User entered 'No (N)'	System	30 Sep 2020 23:04:59

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-30T19:04:40', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'c3d26590-1ab9-46a2-b8c2-c20ef0ea4648'	System	30 Sep 2020 23:04:59
User entered 'None (1)'	System	30 Sep 2020 23:04:59

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:31:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-30T19:04:59', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'c3d26590-1ab9-46a2-b8c2-c20ef0ea4648'	System	30 Sep 2020 23:04:59
User entered '30 Sep 2020 19:04'	System	30 Sep 2020 23:04:59

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Sep 2020 19:01:05
User entered 'Day 3'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-01T19:49:32', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'e9b3fd02-b5e7-4f1b-8d3b-797344c455ce'	System	01 Oct 2020 23:50:17
User entered 'None (1)'	System	01 Oct 2020 23:50:17

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-01T19:49:40', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'e9b3fd02-b5e7-4f1b-8d3b-797344c455ce'	System	01 Oct 2020 23:50:17
User entered 'No (N)'	System	01 Oct 2020 23:50:17

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-01T19:49:46', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'e9b3fd02-b5e7-4f1b-8d3b-797344c455ce'	System	01 Oct 2020 23:50:17
User entered 'No (N)'	System	01 Oct 2020 23:50:17

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-01T19:49:56', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'e9b3fd02-b5e7-4f1b-8d3b-797344c455ce'	System	01 Oct 2020 23:50:17
User entered 'None (1)'	System	01 Oct 2020 23:50:17

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:31:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-01T19:50:17', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'e9b3fd02-b5e7-4f1b-8d3b-797344c455ce'	System	01 Oct 2020 23:50:17
User entered '01 Oct 2020 19:50'	System	01 Oct 2020 23:50:17

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Sep 2020 19:01:05
User entered 'Day 4'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-02T19:03:28', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '3e016f2d-ecdc-4d3e-ad58-6bf2f3f35c3f'	System	02 Oct 2020 23:04:08
User entered 'None (1)'	System	02 Oct 2020 23:04:08

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-02T19:03:34', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '3e016f2d-ecdc-4d3e-ad58-6bf2f3f35c3f'	System	02 Oct 2020 23:04:08
User entered 'No (N)'	System	02 Oct 2020 23:04:08

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-02T19:03:39', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '3e016f2d-ecdc-4d3e-ad58-6bf2f3f35c3f'	System	02 Oct 2020 23:04:08
User entered 'No (N)'	System	02 Oct 2020 23:04:08

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-02T19:03:47', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '3e016f2d-ecdc-4d3e-ad58-6bf2f3f35c3f'	System	02 Oct 2020 23:04:08
User entered 'None (1)'	System	02 Oct 2020 23:04:08

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:31:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-02T19:03:52', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '3e016f2d-ecdc-4d3e-ad58-6bf2f3f35c3f'	System	02 Oct 2020 23:04:08
User entered '02 Oct 2020 19:03'	System	02 Oct 2020 23:04:08

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Sep 2020 19:01:05
User entered 'Day 5'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-03T19:11:43', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '1944bb54-b2a9-4d85-8031-d12e1715bdd5'	System	03 Oct 2020 23:12:13
User entered 'None (1)'	System	03 Oct 2020 23:12:13

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:31:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-03T19:11:56', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '1944bb54-b2a9-4d85-8031-d12e1715bdd5'	System	03 Oct 2020 23:12:13
User entered 'No (N)'	System	03 Oct 2020 23:12:13

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-03T19:12:00', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '1944bb54-b2a9-4d85-8031-d12e1715bdd5'	System	03 Oct 2020 23:12:13
User entered 'No (N)'	System	03 Oct 2020 23:12:13

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-03T19:12:06', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '1944bb54-b2a9-4d85-8031-d12e1715bdd5'	System	03 Oct 2020 23:12:13
User entered 'None (1)'	System	03 Oct 2020 23:12:13

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:31:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-03T19:12:10', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '1944bb54-b2a9-4d85-8031-d12e1715bdd5'	System	03 Oct 2020 23:12:13
User entered '03 Oct 2020 19:12'	System	03 Oct 2020 23:12:13

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Sep 2020 19:01:05
User entered 'Day 6'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-04T19:04:20', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'c58f3f10-bd45-4343-b292-1ccd3f1fa27a'	System	04 Oct 2020 23:04:58
User entered 'None (1)'	System	04 Oct 2020 23:04:58

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-04T19:04:26', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'c58f3f10-bd45-4343-b292-1ccd3f1fa27a'	System	04 Oct 2020 23:04:58
User entered 'No (N)'	System	04 Oct 2020 23:04:58

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-04T19:04:31', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'c58f3f10-bd45-4343-b292-1ccd3f1fa27a'	System	04 Oct 2020 23:04:58
User entered 'No (N)'	System	04 Oct 2020 23:04:58

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-04T19:04:38', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'c58f3f10-bd45-4343-b292-1ccd3f1fa27a'	System	04 Oct 2020 23:04:58
User entered 'None (1)'	System	04 Oct 2020 23:04:58

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:31:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-04T19:04:44', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'c58f3f10-bd45-4343-b292-1ccd3f1fa27a'	System	04 Oct 2020 23:04:58
User entered '04 Oct 2020 19:04'	System	04 Oct 2020 23:04:58

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Sep 2020 19:01:05
User entered 'Day 7'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-05T19:01:38', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'a6d57837-3b7a-4bbf-ae88-cd62ddf48ef1'	System	05 Oct 2020 23:02:08
User entered 'None (1)'	System	05 Oct 2020 23:02:08

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:31:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-05T19:01:43', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'a6d57837-3b7a-4bbf-ae88-cd62ddf48ef1'	System	05 Oct 2020 23:02:08
User entered 'No (N)'	System	05 Oct 2020 23:02:08

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-05T19:01:48', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'a6d57837-3b7a-4bbf-ae88-cd62ddf48ef1'	System	05 Oct 2020 23:02:08
User entered 'No (N)'	System	05 Oct 2020 23:02:08

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-05T19:01:56', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'a6d57837-3b7a-4bbf-ae88-cd62ddf48ef1'	System	05 Oct 2020 23:02:08
User entered 'None (1)'	System	05 Oct 2020 23:02:08

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:31:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-05T19:02:03', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'a6d57837-3b7a-4bbf-ae88-cd62ddf48ef1'	System	05 Oct 2020 23:02:08
User entered '05 Oct 2020 19:02'	System	05 Oct 2020 23:02:08

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Sep 2020 19:01:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-29T15:26:49', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '06a3cc73-2eda-4c96-9fd3-0721b9aa4467'	System	29 Sep 2020 19:27:01
User entered 'None (0)'	System	29 Sep 2020 19:27:01

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-29T15:25:49', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '06a3cc73-2eda-4c96-9fd3-0721b9aa4467'	System	29 Sep 2020 19:27:01
User entered 'None (0)'	System	29 Sep 2020 19:27:01

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-29T15:26:17', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '06a3cc73-2eda-4c96-9fd3-0721b9aa4467'	System	29 Sep 2020 19:27:01
User entered 'None (0)'	System	29 Sep 2020 19:27:01

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-29T15:26:23', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '06a3cc73-2eda-4c96-9fd3-0721b9aa4467'	System	29 Sep 2020 19:27:01
User entered 'None (0)'	System	29 Sep 2020 19:27:01

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-29T15:26:26', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '06a3cc73-2eda-4c96-9fd3-0721b9aa4467'	System	29 Sep 2020 19:27:01
User entered 'None (0)'	System	29 Sep 2020 19:27:01

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-29T15:26:30', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '06a3cc73-2eda-4c96-9fd3-0721b9aa4467'	System	29 Sep 2020 19:27:01
User entered 'None (0)'	System	29 Sep 2020 19:27:01

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-29T15:26:42', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '06a3cc73-2eda-4c96-9fd3-0721b9aa4467'	System	29 Sep 2020 19:27:01
User entered 'No (N)'	System	29 Sep 2020 19:27:01

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-29T15:26:56', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '06a3cc73-2eda-4c96-9fd3-0721b9aa4467'	System	29 Sep 2020 19:27:01
User entered '29 Sep 2020 15:26'	System	29 Sep 2020 19:27:01

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '29 Sep 2020 14:52'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '29 Sep 2020 17:22'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Sep 2020 19:01:05
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-29T20:27:49', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '20173e14-07de-4ccb-a90a-a2cb755faf28'	System	30 Sep 2020 00:28:25
User entered 'None (0)'	System	30 Sep 2020 00:28:25

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-29T20:27:53', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '20173e14-07de-4ccb-a90a-a2cb755faf28'	System	30 Sep 2020 00:28:25
User entered 'None (0)'	System	30 Sep 2020 00:28:25

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-29T20:27:58', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '20173e14-07de-4ccb-a90a-a2cb755faf28'	System	30 Sep 2020 00:28:25
User entered 'None (0)'	System	30 Sep 2020 00:28:25

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-29T20:28:02', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '20173e14-07de-4ccb-a90a-a2cb755faf28'	System	30 Sep 2020 00:28:25
User entered 'None (0)'	System	30 Sep 2020 00:28:25

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-29T20:28:07', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '20173e14-07de-4ccb-a90a-a2cb755faf28'	System	30 Sep 2020 00:28:25
User entered 'None (0)'	System	30 Sep 2020 00:28:25

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-29T20:28:10', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '20173e14-07de-4ccb-a90a-a2cb755faf28'	System	30 Sep 2020 00:28:25
User entered 'None (0)'	System	30 Sep 2020 00:28:25

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-29T20:28:18', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '20173e14-07de-4ccb-a90a-a2cb755faf28'	System	30 Sep 2020 00:28:25
User entered 'No (N)'	System	30 Sep 2020 00:28:25

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-29T20:28:25', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '20173e14-07de-4ccb-a90a-a2cb755faf28'	System	30 Sep 2020 00:28:25
User entered '29 Sep 2020 20:28'	System	30 Sep 2020 00:28:25

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '29 Sep 2020 18:17'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Sep 2020 19:01:05
User entered 'Day 2'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:31:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-30T19:05:09', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'c3a7901d-d75c-40e0-9606-4182caf7633d'	System	30 Sep 2020 23:06:04
User entered 'None (0)'	System	30 Sep 2020 23:06:04

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:31:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-30T19:05:17', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'c3a7901d-d75c-40e0-9606-4182caf7633d'	System	30 Sep 2020 23:06:04
User entered 'None (0)'	System	30 Sep 2020 23:06:04

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:31:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-30T19:05:23', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'c3a7901d-d75c-40e0-9606-4182caf7633d'	System	30 Sep 2020 23:06:04
User entered 'None (0)'	System	30 Sep 2020 23:06:04

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:31:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-30T19:05:31', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'c3a7901d-d75c-40e0-9606-4182caf7633d'	System	30 Sep 2020 23:06:04
User entered 'None (0)'	System	30 Sep 2020 23:06:04

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:31:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-30T19:05:40', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'c3a7901d-d75c-40e0-9606-4182caf7633d'	System	30 Sep 2020 23:06:04
User entered 'None (0)'	System	30 Sep 2020 23:06:04

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:31:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-30T19:05:45', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'c3a7901d-d75c-40e0-9606-4182caf7633d'	System	30 Sep 2020 23:06:04
User entered 'None (0)'	System	30 Sep 2020 23:06:04

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-30T19:05:58', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'c3a7901d-d75c-40e0-9606-4182caf7633d'	System	30 Sep 2020 23:06:04
User entered 'No (N)'	System	30 Sep 2020 23:06:04

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:31:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-09-30T19:06:03', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'c3a7901d-d75c-40e0-9606-4182caf7633d'	System	30 Sep 2020 23:06:04
User entered '30 Sep 2020 19:06'	System	30 Sep 2020 23:06:04

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Sep 2020 19:01:05
User entered 'Day 3'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:31:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-01T19:50:24', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '665bf75c-1a93-422c-b697-b06389e5aacd'	System	01 Oct 2020 23:51:11
User entered 'None (0)'	System	01 Oct 2020 23:51:11

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:31:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-01T19:50:31', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '665bf75c-1a93-422c-b697-b06389e5aacd'	System	01 Oct 2020 23:51:11
User entered 'None (0)'	System	01 Oct 2020 23:51:11

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:31:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-01T19:50:38', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '665bf75c-1a93-422c-b697-b06389e5aacd'	System	01 Oct 2020 23:51:11
User entered 'None (0)'	System	01 Oct 2020 23:51:11

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:31:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-01T19:50:45', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '665bf75c-1a93-422c-b697-b06389e5aacd'	System	01 Oct 2020 23:51:11
User entered 'None (0)'	System	01 Oct 2020 23:51:11

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:31:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-01T19:50:50', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '665bf75c-1a93-422c-b697-b06389e5aacd'	System	01 Oct 2020 23:51:11
User entered 'None (0)'	System	01 Oct 2020 23:51:11

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:31:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-01T19:50:54', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '665bf75c-1a93-422c-b697-b06389e5aacd'	System	01 Oct 2020 23:51:11
User entered 'None (0)'	System	01 Oct 2020 23:51:11

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-01T19:51:03', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '665bf75c-1a93-422c-b697-b06389e5aacd'	System	01 Oct 2020 23:51:11
User entered 'No (N)'	System	01 Oct 2020 23:51:11

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:31:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-01T19:51:08', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '665bf75c-1a93-422c-b697-b06389e5aacd'	System	01 Oct 2020 23:51:11
User entered '01 Oct 2020 19:51'	System	01 Oct 2020 23:51:11

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Sep 2020 19:01:05
User entered 'Day 4'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:31:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-02T19:04:00', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'b6267d3a-25ab-4d5e-ae5e-c272a87363de'	System	02 Oct 2020 23:04:46
User entered 'None (0)'	System	02 Oct 2020 23:04:46

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:31:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-02T19:04:04', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'b6267d3a-25ab-4d5e-ae5e-c272a87363de'	System	02 Oct 2020 23:04:46
User entered 'None (0)'	System	02 Oct 2020 23:04:46

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:31:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-02T19:04:08', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'b6267d3a-25ab-4d5e-ae5e-c272a87363de'	System	02 Oct 2020 23:04:46
User entered 'None (0)'	System	02 Oct 2020 23:04:46

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:31:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-02T19:04:13', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'b6267d3a-25ab-4d5e-ae5e-c272a87363de'	System	02 Oct 2020 23:04:46
User entered 'None (0)'	System	02 Oct 2020 23:04:46

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:31:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-02T19:04:17', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'b6267d3a-25ab-4d5e-ae5e-c272a87363de'	System	02 Oct 2020 23:04:46
User entered 'None (0)'	System	02 Oct 2020 23:04:46

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:31:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-02T19:04:23', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'b6267d3a-25ab-4d5e-ae5e-c272a87363de'	System	02 Oct 2020 23:04:46
User entered 'None (0)'	System	02 Oct 2020 23:04:46

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-02T19:04:29', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'b6267d3a-25ab-4d5e-ae5e-c272a87363de'	System	02 Oct 2020 23:04:46
User entered 'No (N)'	System	02 Oct 2020 23:04:46

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:31:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-02T19:04:33', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'b6267d3a-25ab-4d5e-ae5e-c272a87363de'	System	02 Oct 2020 23:04:46
User entered '02 Oct 2020 19:04'	System	02 Oct 2020 23:04:46

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Sep 2020 19:01:05
User entered 'Day 5'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:31:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-03T19:12:24', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'd23f22ad-3b37-4629-ba9e-95c182ba96da'	System	03 Oct 2020 23:13:07
User entered 'None (0)'	System	03 Oct 2020 23:13:07

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:31:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-03T19:12:35', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'd23f22ad-3b37-4629-ba9e-95c182ba96da'	System	03 Oct 2020 23:13:07
User entered 'None (0)'	System	03 Oct 2020 23:13:07

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:31:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-03T19:12:40', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'd23f22ad-3b37-4629-ba9e-95c182ba96da'	System	03 Oct 2020 23:13:07
User entered 'None (0)'	System	03 Oct 2020 23:13:07

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:31:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-03T19:12:45', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'd23f22ad-3b37-4629-ba9e-95c182ba96da'	System	03 Oct 2020 23:13:07
User entered 'None (0)'	System	03 Oct 2020 23:13:07

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:31:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-03T19:12:49', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'd23f22ad-3b37-4629-ba9e-95c182ba96da'	System	03 Oct 2020 23:13:07
User entered 'None (0)'	System	03 Oct 2020 23:13:07

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:31:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-03T19:12:52', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'd23f22ad-3b37-4629-ba9e-95c182ba96da'	System	03 Oct 2020 23:13:07
User entered 'None (0)'	System	03 Oct 2020 23:13:07

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-03T19:12:57', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'd23f22ad-3b37-4629-ba9e-95c182ba96da'	System	03 Oct 2020 23:13:07
User entered 'No (N)'	System	03 Oct 2020 23:13:07

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:31:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-03T19:13:03', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'd23f22ad-3b37-4629-ba9e-95c182ba96da'	System	03 Oct 2020 23:13:07
User entered '03 Oct 2020 19:13'	System	03 Oct 2020 23:13:07

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Sep 2020 19:01:05
User entered 'Day 6'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:31:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-04T19:04:54', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'd34608b0-109d-4b9b-8aea-fc809f05cb91'	System	04 Oct 2020 23:05:41
User entered 'None (0)'	System	04 Oct 2020 23:05:41

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:31:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-04T19:04:57', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'd34608b0-109d-4b9b-8aea-fc809f05cb91'	System	04 Oct 2020 23:05:41
User entered 'None (0)'	System	04 Oct 2020 23:05:41

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:31:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-04T19:05:04', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'd34608b0-109d-4b9b-8aea-fc809f05cb91'	System	04 Oct 2020 23:05:41
User entered 'None (0)'	System	04 Oct 2020 23:05:41

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:31:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-04T19:05:09', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'd34608b0-109d-4b9b-8aea-fc809f05cb91'	System	04 Oct 2020 23:05:41
User entered 'None (0)'	System	04 Oct 2020 23:05:41

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:31:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-04T19:05:25', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'd34608b0-109d-4b9b-8aea-fc809f05cb91'	System	04 Oct 2020 23:05:41
User entered 'None (0)'	System	04 Oct 2020 23:05:41

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:31:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-04T19:05:28', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'd34608b0-109d-4b9b-8aea-fc809f05cb91'	System	04 Oct 2020 23:05:41
User entered 'None (0)'	System	04 Oct 2020 23:05:41

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-04T19:05:34', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'd34608b0-109d-4b9b-8aea-fc809f05cb91'	System	04 Oct 2020 23:05:41
User entered 'No (N)'	System	04 Oct 2020 23:05:41

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:31:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-04T19:05:37', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'd34608b0-109d-4b9b-8aea-fc809f05cb91'	System	04 Oct 2020 23:05:41
User entered '04 Oct 2020 19:05'	System	04 Oct 2020 23:05:41

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Sep 2020 19:01:05
User entered 'Day 7'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:31:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-05T19:02:11', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '6200f651-2325-4223-ac78-0a20b6782428'	System	05 Oct 2020 23:02:52
User entered 'None (0)'	System	05 Oct 2020 23:02:52

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:31:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-05T19:02:17', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '6200f651-2325-4223-ac78-0a20b6782428'	System	05 Oct 2020 23:02:52
User entered 'None (0)'	System	05 Oct 2020 23:02:52

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:31:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-05T19:02:21', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '6200f651-2325-4223-ac78-0a20b6782428'	System	05 Oct 2020 23:02:52
User entered 'None (0)'	System	05 Oct 2020 23:02:52

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:31:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-05T19:02:27', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '6200f651-2325-4223-ac78-0a20b6782428'	System	05 Oct 2020 23:02:52
User entered 'None (0)'	System	05 Oct 2020 23:02:52

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:31:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-05T19:02:31', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '6200f651-2325-4223-ac78-0a20b6782428'	System	05 Oct 2020 23:02:52
User entered 'None (0)'	System	05 Oct 2020 23:02:52

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:31:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-05T19:02:34', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '6200f651-2325-4223-ac78-0a20b6782428'	System	05 Oct 2020 23:02:52
User entered 'None (0)'	System	05 Oct 2020 23:02:52

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-05T19:02:40', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '6200f651-2325-4223-ac78-0a20b6782428'	System	05 Oct 2020 23:02:52
User entered 'No (N)'	System	05 Oct 2020 23:02:52

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:31:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-05T19:02:50', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '6200f651-2325-4223-ac78-0a20b6782428'	System	05 Oct 2020 23:02:52
User entered '05 Oct 2020 19:02'	System	05 Oct 2020 23:02:52

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 19:01:05

US3952173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 19:01:05

US3952173

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:23
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	09 Oct 2020 14:41:52

US3952173

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:23
User entered '08 Oct 2020'	(b) (4) Nick Bart (b) (4)	09 Oct 2020 14:41:52

US3952173

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Nick Bart (b) (4)	09 Oct 2020 14:41:52

US3952173

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:23
User entered empty.	(b) (4) Nick Bart (b) (4)	09 Oct 2020 14:41:52

US3952173

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:31:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:23
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	09 Oct 2020 14:40:39

US3952173

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:31:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User entered 'I'	System	09 Oct 2020 14:40:39

US3952173

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:23
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	16 Oct 2020 13:22:53

US3952173

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:23
User entered '13 Oct 2020'	(b) (4) Nick Bart (b) (4)	16 Oct 2020 13:22:53

US3952173

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Nick Bart (b) (4)	16 Oct 2020 13:22:53

US3952173

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:23
User entered empty.	(b) (4) Nick Bart (b) (4)	16 Oct 2020 13:22:53

US3952173

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:31:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:23
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	16 Oct 2020 13:22:58

US3952173

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:31:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:44:42
User entered 'I'	System	16 Oct 2020 13:22:58

US3952173

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:01:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:23
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	21 Oct 2020 18:53:07

US3952173

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:01:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:23
User entered '20 Oct 2020'	(b) (4) Nick Bart (b) (4)	21 Oct 2020 18:53:07

US3952173

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:01:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Nick Bart (b) (4)	21 Oct 2020 18:53:07

US3952173

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:01:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:23
User entered empty.	(b) (4) Nick Bart (b) (4)	21 Oct 2020 18:53:07

US3952173

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:31:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:01:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:23
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	21 Oct 2020 18:53:11

US3952173

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:31:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:01:37
User entered 'I'	System	21 Oct 2020 18:53:11

US3952173

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:31:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	04 Nov 2020 19:49:06

US3952173

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '29 Oct 2020'	(b) (4) Nick Bart (b) (4)	04 Nov 2020 19:49:06

US3952173

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'Clinic (Clinic)'	(b) (4) Nick Bart (b) (4)	04 Nov 2020 19:49:06

US3952173

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:31:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User entered 'VISIT2'	System	04 Nov 2020 19:49:06

US3952173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User accepted default value 'Pre-Dose (PREDOSE)'	Nick Bart (b) (4)	04 Nov 2020 19:50:55

US3952173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	04 Nov 2020 19:50:55

US3952173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '29 Oct 2020'	(b) (4) Nick Bart (b) (4)	04 Nov 2020 19:50:55

US3952173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '10:09'	(b) (4) Nick Bart (b) (4)	04 Nov 2020 19:50:55

US3952173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User entered '29 Oct 2020 10:09'	System	04 Nov 2020 19:50:55

US3952173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '36.9' C	(b) (4) Nick Bart (b) (4)	04 Nov 2020 19:50:55

US3952173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'Oral (Oral)'	(b) (4) Nick Bart (b) (4)	04 Nov 2020 19:50:55

US3952173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered empty.	(b) (4) Nick Bart (b) (4)	04 Nov 2020 19:50:55

US3952173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '106'	(b) (4) Nick Bart (b) (4)	04 Nov 2020 19:50:55

US3952173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User entered 'bpm'	System	04 Nov 2020 19:50:55

US3952173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '16'	(b) (4) Nick Bart (b) (4)	04 Nov 2020 19:50:55

US3952173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User entered 'breaths/min'	System	04 Nov 2020 19:50:55

US3952173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '115'	(b) (4) Nick Bart (b) (4)	04 Nov 2020 19:50:55

US3952173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User entered 'mmHg'	System	04 Nov 2020 19:50:55

US3952173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '75'	(b) (4) Nick Bart (b) (4)	04 Nov 2020 19:50:55

US3952173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User entered 'mmHg'	System	04 Nov 2020 19:50:55

US3952173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User accepted default value 'Post-Dose (POSTDOSE)'	Nick Bart (b) (4)	04 Nov 2020 19:50:55

US3952173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	04 Nov 2020 19:50:55

US3952173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '29 Oct 2020'	(b) (4) Nick Bart (b) (4)	04 Nov 2020 19:50:55

US3952173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '11:40'	(b) (4) Nick Bart (b) (4)	04 Nov 2020 19:50:55

US3952173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User entered '29 Oct 2020 11:40'	System	04 Nov 2020 19:50:55

US3952173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '36.9' C	(b) (4) Nick Bart (b) (4)	04 Nov 2020 19:50:55

US3952173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'Oral (Oral)'	(b) (4) Nick Bart (b) (4)	04 Nov 2020 19:50:55

US3952173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered empty.	(b) (4) Nick Bart (b) (4)	04 Nov 2020 19:50:55

US3952173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '97'	(b) (4) Nick Bart (b) (4)	04 Nov 2020 19:50:55

US3952173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User entered 'bpm'	System	04 Nov 2020 19:50:55

US3952173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '18'	(b) (4) Nick Bart (b) (4)	04 Nov 2020 19:50:55

US3952173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User entered 'breaths/min'	System	04 Nov 2020 19:50:55

US3952173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '124'	(b) (4) Nick Bart (b) (4)	04 Nov 2020 19:50:55

US3952173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User entered 'mmHg'	System	04 Nov 2020 19:50:55

US3952173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '80'	(b) (4) Nick Bart (b) (4)	04 Nov 2020 19:50:55

US3952173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User entered 'mmHg'	System	04 Nov 2020 19:50:55

US3952173

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:31:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	04 Nov 2020 19:49:20

US3952173

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:31:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered empty.	(b) (4) Nick Bart (b) (4)	04 Nov 2020 19:49:20

US3952173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:31:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'Yes (Y)'	(b) (4) chrishea Harvey (b) (4)	29 Oct 2020 15:29:54

US3952173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:31:39

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered empty.	(b) (4) chrishea Harvey (b) (4)	29 Oct 2020 15:29:54

US3952173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered empty.	(b) (4) chrishea Harvey (b) (4)	29 Oct 2020 15:29:54

US3952173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:31:39

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User entered 'MRNA-1273 OR PLACEBO'	System	29 Oct 2020 15:29:54

US3952173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:31:39

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '29 Oct 2020'	(b) (4) chrishea Harvey (b) (4)	29 Oct 2020 15:29:54

US3952173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:31:39

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '10:56'	(b) (4) chrishea Harvey (b) (4)	29 Oct 2020 15:29:54

US3952173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:31:39

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User entered '29 Oct 2020 10:56'	System	29 Oct 2020 15:29:54

US3952173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:31:39

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'Left Arm (LEFT ARM)'	(b) (4) chrishea Harvey (b) (4)	29 Oct 2020 15:29:54

US3952173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:31:39

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User entered 'ONCE'	System	29 Oct 2020 15:29:54

US3952173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:31:39

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User entered 'INTRAMUSCULAR'	System	29 Oct 2020 15:29:54

US3952173

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:31:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	04 Nov 2020 19:49:41

US3952173

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:31:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '29 Oct 2020'	(b) (4) Nick Bart (b) (4)	04 Nov 2020 19:49:41

US3952173

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:31:39

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '10:47'	(b) (4) Nick Bart (b) (4)	04 Nov 2020 19:49:41

US3952173

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:31:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User entered '29 Oct 2020 10:47'	System	04 Nov 2020 19:49:41

US3952173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:31:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '29 Oct 2020'	(b) (4) Nick Bart (b) (4)	04 Nov 2020 19:49:54

US3952173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:31:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Nick Bart (b) (4)	04 Nov 2020 19:49:54

US3952173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:31:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	04 Nov 2020 19:49:54

US3952173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:31:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '10:41'	(b) (4) Nick Bart (b) (4)	04 Nov 2020 19:49:54

US3952173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:31:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User entered '29 Oct 2020 10:41'	System	04 Nov 2020 19:49:54

US3952173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:31:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Nick Bart (b) (4)	04 Nov 2020 19:49:54

US3952173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:31:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	04 Nov 2020 19:49:54

US3952173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:31:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered empty.	(b) (4) Nick Bart (b) (4)	04 Nov 2020 19:49:54

US3952173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:31:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User entered empty.	System	04 Nov 2020 19:49:54

US3952173

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:31:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	04 Nov 2020 19:49:12

US3952173

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:31:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User entered '1'	System	04 Nov 2020 19:49:12

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Oct 2020 15:29:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-29T11:42:54', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '377fa328-9d8e-4ded-b49b-388b391b1c6c'	System	29 Oct 2020 15:43:49
User entered 'Yes (Y)'	System	29 Oct 2020 15:43:49

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-29T11:43:24', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '377fa328-9d8e-4ded-b49b-388b391b1c6c'	System	29 Oct 2020 15:43:49
User entered '98.3'	System	29 Oct 2020 15:43:49

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-29T11:43:29', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '377fa328-9d8e-4ded-b49b-388b391b1c6c'	System	29 Oct 2020 15:43:49
User entered 'No (N)'	System	29 Oct 2020 15:43:49

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-29T11:43:45', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '377fa328-9d8e-4ded-b49b-388b391b1c6c'	System	29 Oct 2020 15:43:49
User entered '29 Oct 2020 11:43'	System	29 Oct 2020 15:43:49

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '29 Oct 2020 11:16'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '29 Oct 2020 13:46'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Oct 2020 15:29:54
User entered 'Day 1, after vaccination (at home)'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-29T19:05:38', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'a4f38e7f-04cd-4a69-9962-25a0ff23a7d7'	System	29 Oct 2020 23:06:43
User entered 'Yes (Y)'	System	29 Oct 2020 23:06:43

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-29T19:06:27', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'a4f38e7f-04cd-4a69-9962-25a0ff23a7d7'	System	29 Oct 2020 23:06:43
User entered '95.8'	System	29 Oct 2020 23:06:43

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-29T19:06:35', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'a4f38e7f-04cd-4a69-9962-25a0ff23a7d7'	System	29 Oct 2020 23:06:43
User entered 'No (N)'	System	29 Oct 2020 23:06:43

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-29T19:06:41', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'a4f38e7f-04cd-4a69-9962-25a0ff23a7d7'	System	29 Oct 2020 23:06:43
User entered '29 Oct 2020 19:06'	System	29 Oct 2020 23:06:43

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '29 Oct 2020 14:41'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '30 Oct 2020 11:59'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Oct 2020 15:29:54
User entered 'Day 2'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:31:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-30T19:05:50', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '8cd33208-425b-4bc1-a69c-92574b4f699d'	System	30 Oct 2020 23:07:30
User entered 'Yes (Y)'	System	30 Oct 2020 23:07:30

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:31:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-30T19:07:13', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '8cd33208-425b-4bc1-a69c-92574b4f699d'	System	30 Oct 2020 23:07:30
User entered '96.6'	System	30 Oct 2020 23:07:30

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-30T19:07:20', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '8cd33208-425b-4bc1-a69c-92574b4f699d'	System	30 Oct 2020 23:07:30
User entered 'No (N)'	System	30 Oct 2020 23:07:30

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:31:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-30T19:07:26', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '8cd33208-425b-4bc1-a69c-92574b4f699d'	System	30 Oct 2020 23:07:30
User entered '30 Oct 2020 19:07'	System	30 Oct 2020 23:07:30

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '30 Oct 2020 12:00'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '31 Oct 2020 11:59'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Oct 2020 15:29:54
User entered 'Day 3'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:31:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-31T19:01:22', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '5aa3a22d-97ad-4ff6-bf6f-a1bd8ee48e22'	System	31 Oct 2020 23:02:27
User entered 'Yes (Y)'	System	31 Oct 2020 23:02:27

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:31:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-31T19:02:09', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '5aa3a22d-97ad-4ff6-bf6f-a1bd8ee48e22'	System	31 Oct 2020 23:02:27
User entered '96.1'	System	31 Oct 2020 23:02:27

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-31T19:02:16', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '5aa3a22d-97ad-4ff6-bf6f-a1bd8ee48e22'	System	31 Oct 2020 23:02:27
User entered 'No (N)'	System	31 Oct 2020 23:02:27

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:31:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-31T19:02:23', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '5aa3a22d-97ad-4ff6-bf6f-a1bd8ee48e22'	System	31 Oct 2020 23:02:27
User entered '31 Oct 2020 19:02'	System	31 Oct 2020 23:02:27

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '31 Oct 2020 12:00'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '01 Nov 2020 11:59'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Oct 2020 15:29:54
User entered 'Day 4'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:31:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-01T19:01:19', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '0420c77a-89ef-4a92-9cae-990c3209a401'	System	02 Nov 2020 00:01:55
User entered 'Yes (Y)'	System	02 Nov 2020 00:01:55

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:31:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-01T19:01:41', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '0420c77a-89ef-4a92-9cae-990c3209a401'	System	02 Nov 2020 00:01:55
User entered '95.6'	System	02 Nov 2020 00:01:55

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-01T19:01:45', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '0420c77a-89ef-4a92-9cae-990c3209a401'	System	02 Nov 2020 00:01:55
User entered 'No (N)'	System	02 Nov 2020 00:01:55

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:31:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-01T19:01:51', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '0420c77a-89ef-4a92-9cae-990c3209a401'	System	02 Nov 2020 00:01:55
User entered '01 Nov 2020 19:01'	System	02 Nov 2020 00:01:55

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '01 Nov 2020 12:00'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '02 Nov 2020 11:59'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Oct 2020 15:29:54
User entered 'Day 5'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:31:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-02T19:01:24', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'fcde24fc-3d4f-4610-b6c1-9d4fd1b456f8'	System	03 Nov 2020 00:01:55
User entered 'Yes (Y)'	System	03 Nov 2020 00:01:55

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:31:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-02T19:01:37', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'fcde24fc-3d4f-4610-b6c1-9d4fd1b456f8'	System	03 Nov 2020 00:01:55
User entered '95.8'	System	03 Nov 2020 00:01:55

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-02T19:01:45', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'fcde24fc-3d4f-4610-b6c1-9d4fd1b456f8'	System	03 Nov 2020 00:01:55
User entered 'No (N)'	System	03 Nov 2020 00:01:55

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:31:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-02T19:01:49', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'fcde24fc-3d4f-4610-b6c1-9d4fd1b456f8'	System	03 Nov 2020 00:01:55
User entered '02 Nov 2020 19:01'	System	03 Nov 2020 00:01:55

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '02 Nov 2020 12:00'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '03 Nov 2020 11:59'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Oct 2020 15:29:54
User entered 'Day 6'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:31:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-03T18:59:52', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '28a26cf7-3273-43cf-aa1e-2fdf40773104'	System	04 Nov 2020 00:00:19
User entered 'Yes (Y)'	System	04 Nov 2020 00:00:19

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:31:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-03T19:00:06', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '28a26cf7-3273-43cf-aa1e-2fdf40773104'	System	04 Nov 2020 00:00:19
User entered '95.1'	System	04 Nov 2020 00:00:19

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-03T19:00:12', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '28a26cf7-3273-43cf-aa1e-2fdf40773104'	System	04 Nov 2020 00:00:19
User entered 'No (N)'	System	04 Nov 2020 00:00:19

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:31:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-03T19:00:17', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '28a26cf7-3273-43cf-aa1e-2fdf40773104'	System	04 Nov 2020 00:00:19
User entered '03 Nov 2020 19:00'	System	04 Nov 2020 00:00:19

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '03 Nov 2020 12:00'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '04 Nov 2020 11:59'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Oct 2020 15:29:54
User entered 'Day 7'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:31:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-04T19:00:39', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'e41f74ea-2b76-42e2-a19d-1b92834ef78b'	System	05 Nov 2020 00:01:09
User entered 'Yes (Y)'	System	05 Nov 2020 00:01:09

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:31:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-04T19:00:55', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'e41f74ea-2b76-42e2-a19d-1b92834ef78b'	System	05 Nov 2020 00:01:09
User entered '97.2'	System	05 Nov 2020 00:01:09

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-04T19:00:59', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'e41f74ea-2b76-42e2-a19d-1b92834ef78b'	System	05 Nov 2020 00:01:09
User entered 'No (N)'	System	05 Nov 2020 00:01:09

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:31:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-04T19:01:03', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'e41f74ea-2b76-42e2-a19d-1b92834ef78b'	System	05 Nov 2020 00:01:09
User entered '04 Nov 2020 19:01'	System	05 Nov 2020 00:01:09

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '04 Nov 2020 12:00'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '05 Nov 2020 11:59'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Oct 2020 15:29:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-29T11:44:02', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'd0f51aeb-c147-488a-8feb-05baed7ad903'	System	29 Oct 2020 15:44:25
User entered 'None (1)'	System	29 Oct 2020 15:44:25

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-29T11:44:08', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'd0f51aeb-c147-488a-8feb-05baed7ad903'	System	29 Oct 2020 15:44:25
User entered 'No (N)'	System	29 Oct 2020 15:44:25

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-29T11:44:12', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'd0f51aeb-c147-488a-8feb-05baed7ad903'	System	29 Oct 2020 15:44:25
User entered 'No (N)'	System	29 Oct 2020 15:44:25

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-29T11:44:18', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'd0f51aeb-c147-488a-8feb-05baed7ad903'	System	29 Oct 2020 15:44:25
User entered 'None (1)'	System	29 Oct 2020 15:44:25

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-29T11:44:22', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'd0f51aeb-c147-488a-8feb-05baed7ad903'	System	29 Oct 2020 15:44:25
User entered '29 Oct 2020 11:44'	System	29 Oct 2020 15:44:25

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '29 Oct 2020 11:16'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '29 Oct 2020 13:46'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Oct 2020 15:29:54
User entered 'Day 1, after vaccination (at home)'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-29T19:06:47', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'da014b0b-06e9-4ef9-b810-73b800ee31b3'	System	29 Oct 2020 23:07:12
User entered 'None (1)'	System	29 Oct 2020 23:07:12

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-29T19:06:52', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'da014b0b-06e9-4ef9-b810-73b800ee31b3'	System	29 Oct 2020 23:07:12
User entered 'No (N)'	System	29 Oct 2020 23:07:12

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-29T19:06:56', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'da014b0b-06e9-4ef9-b810-73b800ee31b3'	System	29 Oct 2020 23:07:12
User entered 'No (N)'	System	29 Oct 2020 23:07:12

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-29T19:07:02', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'da014b0b-06e9-4ef9-b810-73b800ee31b3'	System	29 Oct 2020 23:07:12
User entered 'None (1)'	System	29 Oct 2020 23:07:12

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-29T19:07:11', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'da014b0b-06e9-4ef9-b810-73b800ee31b3'	System	29 Oct 2020 23:07:12
User entered '29 Oct 2020 19:07'	System	29 Oct 2020 23:07:12

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '29 Oct 2020 14:41'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '30 Oct 2020 11:59'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Oct 2020 15:29:54
User entered 'Day 2'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-30T19:07:36', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '38b9912a-41dc-4657-8ac4-783290c3bdf8'	System	30 Oct 2020 23:08:01
User entered 'None (1)'	System	30 Oct 2020 23:08:01

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:31:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-30T19:07:41', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '38b9912a-41dc-4657-8ac4-783290c3bdf8'	System	30 Oct 2020 23:08:01
User entered 'No (N)'	System	30 Oct 2020 23:08:01

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-30T19:07:44', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '38b9912a-41dc-4657-8ac4-783290c3bdf8'	System	30 Oct 2020 23:08:01
User entered 'No (N)'	System	30 Oct 2020 23:08:01

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-30T19:07:49', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '38b9912a-41dc-4657-8ac4-783290c3bdf8'	System	30 Oct 2020 23:08:01
User entered 'None (1)'	System	30 Oct 2020 23:08:01

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:31:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-30T19:07:56', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '38b9912a-41dc-4657-8ac4-783290c3bdf8'	System	30 Oct 2020 23:08:01
User entered '30 Oct 2020 19:07'	System	30 Oct 2020 23:08:01

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '30 Oct 2020 12:00'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '31 Oct 2020 11:59'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Oct 2020 15:29:54
User entered 'Day 3'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-31T19:02:31', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'ffeb2563-c2f8-44cb-9916-65a6bd86bc6f'	System	31 Oct 2020 23:03:00
User entered 'None (1)'	System	31 Oct 2020 23:03:00

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:31:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-31T19:02:40', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'ffeb2563-c2f8-44cb-9916-65a6bd86bc6f'	System	31 Oct 2020 23:03:00
User entered 'No (N)'	System	31 Oct 2020 23:03:00

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-31T19:02:44', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'ffeb2563-c2f8-44cb-9916-65a6bd86bc6f'	System	31 Oct 2020 23:03:00
User entered 'No (N)'	System	31 Oct 2020 23:03:00

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-31T19:02:48', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'ffeb2563-c2f8-44cb-9916-65a6bd86bc6f'	System	31 Oct 2020 23:03:00
User entered 'None (1)'	System	31 Oct 2020 23:03:00

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:31:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-31T19:02:53', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'ffeb2563-c2f8-44cb-9916-65a6bd86bc6f'	System	31 Oct 2020 23:03:00
User entered '31 Oct 2020 19:02'	System	31 Oct 2020 23:03:00

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '31 Oct 2020 12:00'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '01 Nov 2020 11:59'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Oct 2020 15:29:54
User entered 'Day 4'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-01T19:01:57', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '02233b39-3afa-4ffb-b553-8e6480a5bd24'	System	02 Nov 2020 00:02:22
User entered 'None (1)'	System	02 Nov 2020 00:02:22

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:31:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-01T19:02:01', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '02233b39-3afa-4ffb-b553-8e6480a5bd24'	System	02 Nov 2020 00:02:22
User entered 'No (N)'	System	02 Nov 2020 00:02:22

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-01T19:02:04', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '02233b39-3afa-4ffb-b553-8e6480a5bd24'	System	02 Nov 2020 00:02:22
User entered 'No (N)'	System	02 Nov 2020 00:02:22

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-01T19:02:09', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '02233b39-3afa-4ffb-b553-8e6480a5bd24'	System	02 Nov 2020 00:02:22
User entered 'None (1)'	System	02 Nov 2020 00:02:22

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:31:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-01T19:02:18', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '02233b39-3afa-4ffb-b553-8e6480a5bd24'	System	02 Nov 2020 00:02:22
User entered '01 Nov 2020 19:02'	System	02 Nov 2020 00:02:22

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '01 Nov 2020 12:00'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '02 Nov 2020 11:59'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Oct 2020 15:29:54
User entered 'Day 5'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-02T19:02:00', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '708ba013-6dd2-497a-a94f-2f739b429f75'	System	03 Nov 2020 00:02:30
User entered 'None (1)'	System	03 Nov 2020 00:02:30

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:31:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-02T19:02:06', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '708ba013-6dd2-497a-a94f-2f739b429f75'	System	03 Nov 2020 00:02:30
User entered 'No (N)'	System	03 Nov 2020 00:02:30

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-02T19:02:13', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '708ba013-6dd2-497a-a94f-2f739b429f75'	System	03 Nov 2020 00:02:30
User entered 'No (N)'	System	03 Nov 2020 00:02:30

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-02T19:02:20', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '708ba013-6dd2-497a-a94f-2f739b429f75'	System	03 Nov 2020 00:02:30
User entered 'None (1)'	System	03 Nov 2020 00:02:30

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:31:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-02T19:02:25', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '708ba013-6dd2-497a-a94f-2f739b429f75'	System	03 Nov 2020 00:02:30
User entered '02 Nov 2020 19:02'	System	03 Nov 2020 00:02:30

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '02 Nov 2020 12:00'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '03 Nov 2020 11:59'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Oct 2020 15:29:54
User entered 'Day 6'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-03T19:00:22', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '03928b05-406a-41c2-b80e-3fda5e0acd9f'	System	04 Nov 2020 00:00:44
User entered 'None (1)'	System	04 Nov 2020 00:00:44

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:31:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-03T19:00:28', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '03928b05-406a-41c2-b80e-3fda5e0acd9f'	System	04 Nov 2020 00:00:44
User entered 'No (N)'	System	04 Nov 2020 00:00:44

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-03T19:00:31', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '03928b05-406a-41c2-b80e-3fda5e0acd9f'	System	04 Nov 2020 00:00:44
User entered 'No (N)'	System	04 Nov 2020 00:00:44

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-03T19:00:35', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '03928b05-406a-41c2-b80e-3fda5e0acd9f'	System	04 Nov 2020 00:00:44
User entered 'None (1)'	System	04 Nov 2020 00:00:44

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:31:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-03T19:00:39', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '03928b05-406a-41c2-b80e-3fda5e0acd9f'	System	04 Nov 2020 00:00:44
User entered '03 Nov 2020 19:00'	System	04 Nov 2020 00:00:44

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '03 Nov 2020 12:00'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '04 Nov 2020 11:59'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Oct 2020 15:29:54
User entered 'Day 7'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-04T19:01:09', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '4f5d9797-c82e-4a44-a296-476e1c5b43c8'	System	05 Nov 2020 00:01:26
User entered 'None (1)'	System	05 Nov 2020 00:01:26

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-04T19:01:12', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '4f5d9797-c82e-4a44-a296-476e1c5b43c8'	System	05 Nov 2020 00:01:26
User entered 'No (N)'	System	05 Nov 2020 00:01:26

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-04T19:01:15', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '4f5d9797-c82e-4a44-a296-476e1c5b43c8'	System	05 Nov 2020 00:01:26
User entered 'No (N)'	System	05 Nov 2020 00:01:26

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-04T19:01:17', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '4f5d9797-c82e-4a44-a296-476e1c5b43c8'	System	05 Nov 2020 00:01:26
User entered 'None (1)'	System	05 Nov 2020 00:01:26

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:31:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-04T19:01:21', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '4f5d9797-c82e-4a44-a296-476e1c5b43c8'	System	05 Nov 2020 00:01:26
User entered '04 Nov 2020 19:01'	System	05 Nov 2020 00:01:26

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '04 Nov 2020 12:00'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '05 Nov 2020 11:59'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Oct 2020 15:29:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-29T11:44:28', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '734efa74-30e8-4f8e-b8ab-9c25ed764b7d'	System	29 Oct 2020 15:45:03
User entered 'None (0)'	System	29 Oct 2020 15:45:03

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-29T11:44:31', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '734efa74-30e8-4f8e-b8ab-9c25ed764b7d'	System	29 Oct 2020 15:45:03
User entered 'None (0)'	System	29 Oct 2020 15:45:03

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-29T11:44:34', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '734efa74-30e8-4f8e-b8ab-9c25ed764b7d'	System	29 Oct 2020 15:45:03
User entered 'None (0)'	System	29 Oct 2020 15:45:03

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-29T11:44:37', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '734efa74-30e8-4f8e-b8ab-9c25ed764b7d'	System	29 Oct 2020 15:45:03
User entered 'None (0)'	System	29 Oct 2020 15:45:03

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-29T11:44:40', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '734efa74-30e8-4f8e-b8ab-9c25ed764b7d'	System	29 Oct 2020 15:45:03
User entered 'None (0)'	System	29 Oct 2020 15:45:03

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-29T11:44:43', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '734efa74-30e8-4f8e-b8ab-9c25ed764b7d'	System	29 Oct 2020 15:45:03
User entered 'None (0)'	System	29 Oct 2020 15:45:03

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-29T11:44:52', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '734efa74-30e8-4f8e-b8ab-9c25ed764b7d'	System	29 Oct 2020 15:45:03
User entered 'No (N)'	System	29 Oct 2020 15:45:03

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-29T11:44:56', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '734efa74-30e8-4f8e-b8ab-9c25ed764b7d'	System	29 Oct 2020 15:45:03
User entered '29 Oct 2020 11:44'	System	29 Oct 2020 15:45:03

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '29 Oct 2020 11:16'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '29 Oct 2020 13:46'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Oct 2020 15:29:54
User entered 'Day 1, after vaccination (at home)'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-29T19:07:19', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'b257c569-5774-4a95-99a9-dba016c24304'	System	29 Oct 2020 23:07:51
User entered 'None (0)'	System	29 Oct 2020 23:07:51

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-29T19:07:22', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'b257c569-5774-4a95-99a9-dba016c24304'	System	29 Oct 2020 23:07:51
User entered 'None (0)'	System	29 Oct 2020 23:07:51

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-29T19:07:25', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'b257c569-5774-4a95-99a9-dba016c24304'	System	29 Oct 2020 23:07:51
User entered 'None (0)'	System	29 Oct 2020 23:07:51

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-29T19:07:28', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'b257c569-5774-4a95-99a9-dba016c24304'	System	29 Oct 2020 23:07:51
User entered 'None (0)'	System	29 Oct 2020 23:07:51

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-29T19:07:31', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'b257c569-5774-4a95-99a9-dba016c24304'	System	29 Oct 2020 23:07:51
User entered 'None (0)'	System	29 Oct 2020 23:07:51

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-29T19:07:36', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'b257c569-5774-4a95-99a9-dba016c24304'	System	29 Oct 2020 23:07:51
User entered 'None (0)'	System	29 Oct 2020 23:07:51

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-29T19:07:44', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'b257c569-5774-4a95-99a9-dba016c24304'	System	29 Oct 2020 23:07:51
User entered 'No (N)'	System	29 Oct 2020 23:07:51

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-29T19:07:49', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'b257c569-5774-4a95-99a9-dba016c24304' User entered '29 Oct 2020 19:07'	System	29 Oct 2020 23:07:51
	System	29 Oct 2020 23:07:51

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '29 Oct 2020 14:41'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '30 Oct 2020 11:59'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Oct 2020 15:29:54
User entered 'Day 2'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:31:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-30T19:08:02', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '7d4762fb-7b91-4064-b327-efb8d74d30cf'	System	30 Oct 2020 23:08:31
User entered 'None (0)'	System	30 Oct 2020 23:08:31

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:31:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-30T19:08:05', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '7d4762fb-7b91-4064-b327-efb8d74d30cf'	System	30 Oct 2020 23:08:31
User entered 'None (0)'	System	30 Oct 2020 23:08:31

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:31:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-30T19:08:08', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '7d4762fb-7b91-4064-b327-efb8d74d30cf'	System	30 Oct 2020 23:08:31
User entered 'None (0)'	System	30 Oct 2020 23:08:31

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:31:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-30T19:08:11', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '7d4762fb-7b91-4064-b327-efb8d74d30cf'	System	30 Oct 2020 23:08:31
User entered 'None (0)'	System	30 Oct 2020 23:08:31

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:31:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-30T19:08:15', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '7d4762fb-7b91-4064-b327-efb8d74d30cf'	System	30 Oct 2020 23:08:31
User entered 'None (0)'	System	30 Oct 2020 23:08:31

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:31:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-30T19:08:18', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '7d4762fb-7b91-4064-b327-efb8d74d30cf'	System	30 Oct 2020 23:08:31
User entered 'None (0)'	System	30 Oct 2020 23:08:31

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-30T19:08:24', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '7d4762fb-7b91-4064-b327-efb8d74d30cf'	System	30 Oct 2020 23:08:31
User entered 'No (N)'	System	30 Oct 2020 23:08:31

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:31:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-30T19:08:28', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '7d4762fb-7b91-4064-b327-efb8d74d30cf'	System	30 Oct 2020 23:08:31
User entered '30 Oct 2020 19:08'	System	30 Oct 2020 23:08:31

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '30 Oct 2020 12:00'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '31 Oct 2020 11:59'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Oct 2020 15:29:54
User entered 'Day 3'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:31:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-31T19:03:02', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '43cf0034-129d-4566-b4a8-edb467077eb5'	System	31 Oct 2020 23:03:30
User entered 'None (0)'	System	31 Oct 2020 23:03:30

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:31:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-31T19:03:06', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '43cf0034-129d-4566-b4a8-edb467077eb5'	System	31 Oct 2020 23:03:30
User entered 'None (0)'	System	31 Oct 2020 23:03:30

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:31:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-31T19:03:09', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '43cf0034-129d-4566-b4a8-edb467077eb5'	System	31 Oct 2020 23:03:30
User entered 'None (0)'	System	31 Oct 2020 23:03:30

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:31:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-31T19:03:12', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '43cf0034-129d-4566-b4a8-edb467077eb5'	System	31 Oct 2020 23:03:30
User entered 'None (0)'	System	31 Oct 2020 23:03:30

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:31:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-31T19:03:15', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '43cf0034-129d-4566-b4a8-edb467077eb5'	System	31 Oct 2020 23:03:30
User entered 'None (0)'	System	31 Oct 2020 23:03:30

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:31:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-31T19:03:18', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '43cf0034-129d-4566-b4a8-edb467077eb5'	System	31 Oct 2020 23:03:30
User entered 'None (0)'	System	31 Oct 2020 23:03:30

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-31T19:03:23', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '43cf0034-129d-4566-b4a8-edb467077eb5'	System	31 Oct 2020 23:03:30
User entered 'No (N)'	System	31 Oct 2020 23:03:30

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:31:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-10-31T19:03:26', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '43cf0034-129d-4566-b4a8-edb467077eb5'	System	31 Oct 2020 23:03:30
User entered '31 Oct 2020 19:03'	System	31 Oct 2020 23:03:30

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '31 Oct 2020 12:00'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '01 Nov 2020 11:59'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Oct 2020 15:29:54
User entered 'Day 4'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:31:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-01T19:02:27', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '7c85ff05-1b2c-4fd2-a07c-f92488febf91'	System	02 Nov 2020 00:02:56
User entered 'None (0)'	System	02 Nov 2020 00:02:56

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:31:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-01T19:02:30', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '7c85ff05-1b2c-4fd2-a07c-f92488febf91'	System	02 Nov 2020 00:02:56
User entered 'None (0)'	System	02 Nov 2020 00:02:56

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:31:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-01T19:02:33', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '7c85ff05-1b2c-4fd2-a07c-f92488febf91'	System	02 Nov 2020 00:02:56
User entered 'None (0)'	System	02 Nov 2020 00:02:56

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:31:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-01T19:02:36', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '7c85ff05-1b2c-4fd2-a07c-f92488febf91'	System	02 Nov 2020 00:02:56
User entered 'None (0)'	System	02 Nov 2020 00:02:56

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:31:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-01T19:02:39', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '7c85ff05-1b2c-4fd2-a07c-f92488febf91'	System	02 Nov 2020 00:02:56
User entered 'None (0)'	System	02 Nov 2020 00:02:56

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:31:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-01T19:02:41', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '7c85ff05-1b2c-4fd2-a07c-f92488febf91'	System	02 Nov 2020 00:02:56
User entered 'None (0)'	System	02 Nov 2020 00:02:56

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-01T19:02:48', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '7c85ff05-1b2c-4fd2-a07c-f92488febf91'	System	02 Nov 2020 00:02:56
User entered 'No (N)'	System	02 Nov 2020 00:02:56

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:31:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-01T19:02:52', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '7c85ff05-1b2c-4fd2-a07c-f92488febf91'	System	02 Nov 2020 00:02:56
User entered '01 Nov 2020 19:02'	System	02 Nov 2020 00:02:56

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '01 Nov 2020 12:00'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '02 Nov 2020 11:59'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Oct 2020 15:29:54
User entered 'Day 5'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:31:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-02T19:02:30', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '43c0b954-a3c6-4729-ae9f-cf9086d2ecef'	System	03 Nov 2020 00:03:04
User entered 'None (0)'	System	03 Nov 2020 00:03:04

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:31:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-02T19:02:33', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '43c0b954-a3c6-4729-ae9f-cf9086d2ecef'	System	03 Nov 2020 00:03:04
User entered 'None (0)'	System	03 Nov 2020 00:03:04

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:31:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-02T19:02:37', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '43c0b954-a3c6-4729-ae9f-cf9086d2ecef'	System	03 Nov 2020 00:03:04
User entered 'None (0)'	System	03 Nov 2020 00:03:04

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:31:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-02T19:02:42', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '43c0b954-a3c6-4729-ae9f-cf9086d2ecef'	System	03 Nov 2020 00:03:04
User entered 'None (0)'	System	03 Nov 2020 00:03:04

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:31:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-02T19:02:45', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '43c0b954-a3c6-4729-ae9f-cf9086d2ecef'	System	03 Nov 2020 00:03:04
User entered 'None (0)'	System	03 Nov 2020 00:03:04

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:31:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-02T19:02:48', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '43c0b954-a3c6-4729-ae9f-cf9086d2ecef'	System	03 Nov 2020 00:03:04
User entered 'None (0)'	System	03 Nov 2020 00:03:04

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-02T19:02:56', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '43c0b954-a3c6-4729-ae9f-cf9086d2ecef'	System	03 Nov 2020 00:03:04
User entered 'No (N)'	System	03 Nov 2020 00:03:04

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:31:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-02T19:02:59', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '43c0b954-a3c6-4729-ae9f-cf9086d2ecef'	System	03 Nov 2020 00:03:04
User entered '02 Nov 2020 19:02'	System	03 Nov 2020 00:03:04

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '02 Nov 2020 12:00'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '03 Nov 2020 11:59'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Oct 2020 15:29:54
User entered 'Day 6'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:31:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-03T19:00:44', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '677440a2-b7db-468f-bb99-26bc27d21ace'	System	04 Nov 2020 00:01:12
User entered 'None (0)'	System	04 Nov 2020 00:01:12

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:31:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-03T19:00:46', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '677440a2-b7db-468f-bb99-26bc27d21ace'	System	04 Nov 2020 00:01:12
User entered 'None (0)'	System	04 Nov 2020 00:01:12

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:31:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-03T19:00:49', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '677440a2-b7db-468f-bb99-26bc27d21ace'	System	04 Nov 2020 00:01:12
User entered 'None (0)'	System	04 Nov 2020 00:01:12

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:31:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-03T19:00:52', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '677440a2-b7db-468f-bb99-26bc27d21ace'	System	04 Nov 2020 00:01:12
User entered 'None (0)'	System	04 Nov 2020 00:01:12

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:31:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-03T19:00:54', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '677440a2-b7db-468f-bb99-26bc27d21ace'	System	04 Nov 2020 00:01:12
User entered 'None (0)'	System	04 Nov 2020 00:01:12

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:31:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-03T19:00:56', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '677440a2-b7db-468f-bb99-26bc27d21ace'	System	04 Nov 2020 00:01:12
User entered 'None (0)'	System	04 Nov 2020 00:01:12

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-03T19:01:04', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '677440a2-b7db-468f-bb99-26bc27d21ace'	System	04 Nov 2020 00:01:12
User entered 'No (N)'	System	04 Nov 2020 00:01:12

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:31:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-03T19:01:06', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '677440a2-b7db-468f-bb99-26bc27d21ace'	System	04 Nov 2020 00:01:12
User entered '03 Nov 2020 19:01'	System	04 Nov 2020 00:01:12

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '03 Nov 2020 12:00'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '04 Nov 2020 11:59'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
Data entry locked.	System	29 Oct 2020 15:29:54
User entered 'Day 7'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:31:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-04T19:01:26', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '806d74de-9df1-4cfc-bbd3-30c879a7bf19'	System	05 Nov 2020 00:01:46
User entered 'None (0)'	System	05 Nov 2020 00:01:46

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:31:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-04T19:01:28', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '806d74de-9df1-4cfc-bbd3-30c879a7bf19'	System	05 Nov 2020 00:01:46
User entered 'None (0)'	System	05 Nov 2020 00:01:46

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:31:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-04T19:01:30', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '806d74de-9df1-4cfc-bbd3-30c879a7bf19'	System	05 Nov 2020 00:01:46
User entered 'None (0)'	System	05 Nov 2020 00:01:46

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:31:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-04T19:01:33', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '806d74de-9df1-4cfc-bbd3-30c879a7bf19'	System	05 Nov 2020 00:01:46
User entered 'None (0)'	System	05 Nov 2020 00:01:46

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:31:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-04T19:01:36', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '806d74de-9df1-4cfc-bbd3-30c879a7bf19'	System	05 Nov 2020 00:01:46
User entered 'None (0)'	System	05 Nov 2020 00:01:46

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:31:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-04T19:01:38', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '806d74de-9df1-4cfc-bbd3-30c879a7bf19'	System	05 Nov 2020 00:01:46
User entered 'None (0)'	System	05 Nov 2020 00:01:46

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:31:39

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 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-04T19:01:40', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '806d74de-9df1-4cfc-bbd3-30c879a7bf19'	System	05 Nov 2020 00:01:46
User entered 'No (N)'	System	05 Nov 2020 00:01:46

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:31:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-11-04T19:01:43', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '806d74de-9df1-4cfc-bbd3-30c879a7bf19'	System	05 Nov 2020 00:01:46
User entered '04 Nov 2020 19:01'	System	05 Nov 2020 00:01:46

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:31:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '04 Nov 2020 12:00'	System	29 Oct 2020 15:29:54

US3952173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:31:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:54
User entered '05 Nov 2020 11:59'	System	29 Oct 2020 15:29:54

US3952173

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:49:02
User entered 'Yes (Y)'	Brianne Okunji (b) (4)	05 Nov 2020 23:27:46

US3952173

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:49:02
User entered '05 Nov 2020'	Brianne Okunji (b) (4)	05 Nov 2020 23:27:46

US3952173

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:49:02
User entered 'Contact Made (CONTACT MADE)'	Brianne Okunji (b) (4)	05 Nov 2020 23:27:46

US3952173

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:49:02
User entered empty.	Brianne Okunji (b) (4)	05 Nov 2020 23:27:46

US3952173

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:31:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:49:02
User entered 'Yes (Y)'	Brianne Okunji (b) (4)	05 Nov 2020 23:27:57

US3952173

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:31:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User entered 'I'	System	05 Nov 2020 23:27:57

US3952173

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:23
User entered 'Yes (Y)'	(b) (4) Brianne Okunji (b) (4) (b) (4)	13 Nov 2020 00:12:03

US3952173

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:23
User entered '12 Nov 2020'	Brianne Okunji (b) (4)	13 Nov 2020 00:12:03

US3952173

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Brianne Okunji (b) (4) (b) (4)	13 Nov 2020 00:12:03

US3952173

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:23
User entered empty.	Brianne Okunji (b) (4)	13 Nov 2020 00:12:03

US3952173

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:31:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:23
User entered 'Yes (Y)'	(b) (4) Brianne Okunji (b) (4) (b) (4)	13 Nov 2020 00:12:21

US3952173

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:31:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User entered 'I'	System	13 Nov 2020 00:12:21

US3952173

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:23
User entered 'Yes (Y)'	(b) (4) Brianne Okunji (b) (4) (b) (4)	20 Nov 2020 23:02:22

US3952173

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:23
User entered '20 Nov 2020'	Brianne Okunji (b) (4)	20 Nov 2020 23:02:22

US3952173

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:23
User entered 'Contact Made (CONTACT MADE)'	Brianne Okunji (b) (4)	20 Nov 2020 23:02:22

US3952173

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:23
User entered empty.	Brianne Okunji (b) (4)	20 Nov 2020 23:02:22

US3952173

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:31:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:23
User entered 'Yes (Y)'	(b) (4) Brianne Okunji (b) (4) (b) (4)	20 Nov 2020 23:02:28

US3952173

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:31:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User entered 'I'	System	20 Nov 2020 23:02:28

US3952173

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:31:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	25 Nov 2020 18:48:17

US3952173

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '24 Nov 2020'	(b) (4) Nick Bart (b) (4)	25 Nov 2020 18:48:17

US3952173

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'Clinic (Clinic)'	(b) (4) Nick Bart (b) (4)	25 Nov 2020 18:48:17

US3952173

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:31:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User entered 'VISIT3'	System	25 Nov 2020 18:48:17

US3952173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:31:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	25 Nov 2020 18:48:27

US3952173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:31:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered empty.	(b) (4) Nick Bart (b) (4)	25 Nov 2020 18:48:27

US3952173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered empty.	(b) (4) Nick Bart (b) (4)	25 Nov 2020 18:48:27

US3952173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User entered empty.	System	25 Nov 2020 18:48:27

US3952173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered empty.	(b) (4) Nick Bart (b) (4)	25 Nov 2020 18:48:27

US3952173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:31:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered empty.	(b) (4) Nick Bart (b) (4)	25 Nov 2020 18:48:27

US3952173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:31:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered empty.	(b) (4) Nick Bart (b) (4)	25 Nov 2020 18:48:27

US3952173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:31:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered empty.	(b) (4) Nick Bart (b) (4)	25 Nov 2020 18:48:27

US3952173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:31:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User entered empty.	System	25 Nov 2020 18:48:27

US3952173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered empty.	(b) (4) Nick Bart (b) (4)	25 Nov 2020 18:48:27

US3952173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:31:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User entered empty.	System	25 Nov 2020 18:48:27

US3952173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered empty.	(b) (4) Nick Bart (b) (4)	25 Nov 2020 18:48:27

US3952173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:31:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User entered empty.	System	25 Nov 2020 18:48:27

US3952173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered empty.	(b) (4) Nick Bart (b) (4)	25 Nov 2020 18:48:27

US3952173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:31:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User entered empty.	System	25 Nov 2020 18:48:27

US3952173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:31:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14

US3952173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:31:39

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14

US3952173

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:31:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	25 Nov 2020 18:48:32

US3952173

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:31:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered empty.	(b) (4) Nick Bart (b) (4)	25 Nov 2020 18:48:32

US3952173

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:31:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	25 Nov 2020 18:48:52

US3952173

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:31:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '24 Nov 2020'	(b) (4) Nick Bart (b) (4)	25 Nov 2020 18:48:52

US3952173

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:31:39

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered '14:55'	(b) (4) Nick Bart (b) (4)	25 Nov 2020 18:48:52

US3952173

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:31:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User entered '24 Nov 2020 14:55'	System	25 Nov 2020 18:48:52

US3952173

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:31:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:16:27
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	25 Nov 2020 18:48:36

US3952173

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:31:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User entered '1'	System	25 Nov 2020 18:48:36

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[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 (479c3cf623e593b0)', Time: '2020-12-03T06:15:14', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '6fdd750a-97d6-40ac-b2cf-bde192968a55'	System	03 Dec 2020 11:16:15
User entered 'No (N)'	System	03 Dec 2020 11:16:15

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Have you been exposed to someone with 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 (479c3cf623e593b0)', Time: '2020-12-03T06:15:36', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '6fdd750a-97d6-40ac-b2cf-bde192968a55'	System	03 Dec 2020 11:16:15
User entered 'No (N)'	System	03 Dec 2020 11:16:15

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-12-03T06:16:12', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '6fdd750a-97d6-40ac-b2cf-bde192968a55'	System	03 Dec 2020 11:16:15
User entered '03 Dec 2020 06:16:12'	System	03 Dec 2020 11:16:15

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[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 (479c3cf623e593b0)', Time: '2020-12-10T09:42:45', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'fae42912-9516-4d9c-9dbd-8ac598c29f31'	System	10 Dec 2020 14:43:00
User entered 'No (N)'	System	10 Dec 2020 14:43:00

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Have you been exposed to someone with 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 (479c3cf623e593b0)', Time: '2020-12-10T09:42:51', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'fae42912-9516-4d9c-9dbd-8ac598c29f31'	System	10 Dec 2020 14:43:00
User entered 'No (N)'	System	10 Dec 2020 14:43:00

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-12-10T09:43:00', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'fae42912-9516-4d9c-9dbd-8ac598c29f31'	System	10 Dec 2020 14:43:00
User entered '10 Dec 2020 09:43:00'	System	10 Dec 2020 14:43:00

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[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 (479c3cf623e593b0)', Time: '2020-12-17T08:02:53', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '5bf19d44-442c-4ce6-bdb5-b129dafbc2e0'	System	17 Dec 2020 13:03:35
User entered 'No (N)'	System	17 Dec 2020 13:03:35

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

Have you been exposed to someone with 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 (479c3cf623e593b0)', Time: '2020-12-17T08:03:08', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '5bf19d44-442c-4ce6-bdb5-b129dafbc2e0'	System	17 Dec 2020 13:03:35
User entered 'No (N)'	System	17 Dec 2020 13:03:35

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-12-17T08:03:36', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '5bf19d44-442c-4ce6-bdb5-b129dafbc2e0' User entered '17 Dec 2020 08:03:36'	System	17 Dec 2020 13:03:35
	System	17 Dec 2020 13:03:35

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[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 (479c3cf623e593b0)', Time: '2020-12-24T09:16:58', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '4254ed8f-a359-4e75-bd66-7e243b8680df'	System	24 Dec 2020 14:17:10
User entered 'No (N)'	System	24 Dec 2020 14:17:10

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

Have you been exposed to someone with 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 (479c3cf623e593b0)', Time: '2020-12-24T09:17:03', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '4254ed8f-a359-4e75-bd66-7e243b8680df'	System	24 Dec 2020 14:17:10
User entered 'No (N)'	System	24 Dec 2020 14:17:10

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-12-24T09:17:08', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '4254ed8f-a359-4e75-bd66-7e243b8680df' User entered '24 Dec 2020 09:17:08'	System	24 Dec 2020 14:17:10
	System	24 Dec 2020 14:17:10

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[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 (479c3cf623e593b0)', Time: '2020-12-31T08:52:49', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '9edb1ade-b402-46ea-8fde-52aed3c39791'	System	31 Dec 2020 13:53:25
User entered 'No (N)'	System	31 Dec 2020 13:53:25

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

Have you been exposed to someone with 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 (479c3cf623e593b0)', Time: '2020-12-31T08:52:59', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '9edb1ade-b402-46ea-8fde-52aed3c39791'	System	31 Dec 2020 13:53:25
User entered 'No (N)'	System	31 Dec 2020 13:53:25

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2020-12-31T08:53:19', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '9edb1ade-b402-46ea-8fde-52aed3c39791'	System	31 Dec 2020 13:53:25
User entered '31 Dec 2020 08:53:19'	System	31 Dec 2020 13:53:25

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[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 (479c3cf623e593b0)', Time: '2021-01-07T17:34:09', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '37b96cdc-5485-4e04-9d22-eafd2e15aad2'	System	07 Jan 2021 22:34:36
User entered 'No (N)'	System	07 Jan 2021 22:34:36

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

Have you been exposed to someone with 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 (479c3cf623e593b0)', Time: '2021-01-07T17:34:20', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '37b96cdc-5485-4e04-9d22-eafd2e15aad2'	System	07 Jan 2021 22:34:36
User entered 'No (N)'	System	07 Jan 2021 22:34:36

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2021-01-07T17:34:30', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '37b96cdc-5485-4e04-9d22-eafd2e15aad2' User entered '07 Jan 2021 17:34:30'	System	07 Jan 2021 22:34:36
	System	07 Jan 2021 22:34:36

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[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 (479c3cf623e593b0)', Time: '2021-01-14T09:20:07', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'fb7c71b0-ce77-4c3b-8f19-fbf9fb466dab'	System	14 Jan 2021 14:20:19
User entered 'No (N)'	System	14 Jan 2021 14:20:19

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

Have you been exposed to someone with 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 (479c3cf623e593b0)', Time: '2021-01-14T09:20:12', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'fb7c71b0-ce77-4c3b-8f19-fbf9fb466dab'	System	14 Jan 2021 14:20:19
User entered 'No (N)'	System	14 Jan 2021 14:20:19

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2021-01-14T09:20:17', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'fb7c71b0-ce77-4c3b-8f19-fbf9fb466dab'	System	14 Jan 2021 14:20:19
User entered '14 Jan 2021 09:20:17'	System	14 Jan 2021 14:20:19

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[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 (479c3cf623e593b0)', Time: '2021-01-21T20:41:15', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '2ca6dfac-b4ba-4f93-9174-207e5a18550c'	System	22 Jan 2021 01:41:58
User entered 'No (N)'	System	22 Jan 2021 01:41:58

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

Have you been exposed to someone with 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 (479c3cf623e593b0)', Time: '2021-01-21T20:41:46', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '2ca6dfac-b4ba-4f93-9174-207e5a18550c'	System	22 Jan 2021 01:41:58
User entered 'No (N)'	System	22 Jan 2021 01:41:58

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2021-01-21T20:41:54', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '2ca6dfac-b4ba-4f93-9174-207e5a18550c' User entered '21 Jan 2021 20:41:54'	System	22 Jan 2021 01:41:58

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[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 (479c3cf623e593b0)', Time: '2021-01-28T08:47:42', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'f6d51d1f-72ad-4d81-8c60-3d2e99ce5f04'	System	28 Jan 2021 13:48:07
User entered 'No (N)'	System	28 Jan 2021 13:48:07

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Have you been exposed to someone with 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 (479c3cf623e593b0)', Time: '2021-01-28T08:47:51', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'f6d51d1f-72ad-4d81-8c60-3d2e99ce5f04'	System	28 Jan 2021 13:48:07
User entered 'No (N)'	System	28 Jan 2021 13:48:07

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2021-01-28T08:48:04', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'f6d51d1f-72ad-4d81-8c60-3d2e99ce5f04'	System	28 Jan 2021 13:48:07
User entered '28 Jan 2021 08:48:04'	System	28 Jan 2021 13:48:07

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[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 (479c3cf623e593b0)', Time: '2021-02-04T07:55:14', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'a48f703c-0c3b-41fd-a7bd-42d43d73635e'	System	04 Feb 2021 12:55:29
User entered 'No (N)'	System	04 Feb 2021 12:55:29

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

Have you been exposed to someone with 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 (479c3cf623e593b0)', Time: '2021-02-04T07:55:18', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'a48f703c-0c3b-41fd-a7bd-42d43d73635e'	System	04 Feb 2021 12:55:29
User entered 'No (N)'	System	04 Feb 2021 12:55:29

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2021-02-04T07:55:24', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'a48f703c-0c3b-41fd-a7bd-42d43d73635e'	System	04 Feb 2021 12:55:29
User entered '04 Feb 2021 07:55:24'	System	04 Feb 2021 12:55:29

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[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 (479c3cf623e593b0)', Time: '2021-02-11T12:51:18', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '195027ed-5b04-48b1-883a-2dfb817497ed'	System	11 Feb 2021 17:51:36
User entered 'No (N)'	System	11 Feb 2021 17:51:36

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

Have you been exposed to someone with 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 (479c3cf623e593b0)', Time: '2021-02-11T12:51:30', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '195027ed-5b04-48b1-883a-2dfb817497ed'	System	11 Feb 2021 17:51:36
User entered 'No (N)'	System	11 Feb 2021 17:51:36

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2021-02-11T12:51:35', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '195027ed-5b04-48b1-883a-2dfb817497ed'	System	11 Feb 2021 17:51:36
User entered '11 Feb 2021 12:51:35'	System	11 Feb 2021 17:51:36

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[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 (479c3cf623e593b0)', Time: '2021-02-18T17:09:04', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'fe2b500f-dca0-4167-ba7d-f73ee0056fba'	System	18 Feb 2021 22:09:24
User entered 'No (N)'	System	18 Feb 2021 22:09:24

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

Have you been exposed to someone with 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 (479c3cf623e593b0)', Time: '2021-02-18T17:09:10', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'fe2b500f-dca0-4167-ba7d-f73ee0056fba'	System	18 Feb 2021 22:09:24
User entered 'No (N)'	System	18 Feb 2021 22:09:24

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2021-02-18T17:09:18', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'fe2b500f-dca0-4167-ba7d-f73ee0056fba' User entered '18 Feb 2021 17:09:18'	System	18 Feb 2021 22:09:24

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[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 (479c3cf623e593b0)', Time: '2021-02-25T09:48:56', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '2322ec18-d812-4a3f-ace0-eb764789327e'	System	25 Feb 2021 14:49:10
User entered 'No (N)'	System	25 Feb 2021 14:49:10

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

Have you been exposed to someone with 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 (479c3cf623e593b0)', Time: '2021-02-25T09:48:59', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '2322ec18-d812-4a3f-ace0-eb764789327e'	System	25 Feb 2021 14:49:10
User entered 'No (N)'	System	25 Feb 2021 14:49:10

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2021-02-25T09:49:07', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '2322ec18-d812-4a3f-ace0-eb764789327e'	System	25 Feb 2021 14:49:10
User entered '25 Feb 2021 09:49:07'	System	25 Feb 2021 14:49:10

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[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 (479c3cf623e593b0)', Time: '2021-03-04T09:05:08', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '506e84a3-0e72-4604-ad08-60e9d7eba849'	System	04 Mar 2021 14:05:28
User entered 'No (N)'	System	04 Mar 2021 14:05:28

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

Have you been exposed to someone with 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 (479c3cf623e593b0)', Time: '2021-03-04T09:05:12', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '506e84a3-0e72-4604-ad08-60e9d7eba849'	System	04 Mar 2021 14:05:28
User entered 'No (N)'	System	04 Mar 2021 14:05:28

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2021-03-04T09:05:20', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '506e84a3-0e72-4604-ad08-60e9d7eba849'	System	04 Mar 2021 14:05:28
User entered '04 Mar 2021 09:05:20'	System	04 Mar 2021 14:05:28

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[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 (479c3cf623e593b0)', Time: '2021-03-11T08:35:03', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'aa1c6e03-132f-4d57-8fee-081deca19ed4'	System	11 Mar 2021 13:35:22
User entered 'No (N)'	System	11 Mar 2021 13:35:22

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

Have you been exposed to someone with 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 (479c3cf623e593b0)', Time: '2021-03-11T08:34:51', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'aa1c6e03-132f-4d57-8fee-081deca19ed4'	System	11 Mar 2021 13:35:22
User entered 'No (N)'	System	11 Mar 2021 13:35:22

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2021-03-11T08:35:17', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'aa1c6e03-132f-4d57-8fee-081deca19ed4'	System	11 Mar 2021 13:35:22
User entered '11 Mar 2021 08:35:17'	System	11 Mar 2021 13:35:22

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[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 (479c3cf623e593b0)', Time: '2021-03-18T10:49:27', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '95e8d46f-bc2b-4ac9-8513-1e17be7d91df'	System	18 Mar 2021 14:49:43
User entered 'No (N)'	System	18 Mar 2021 14:49:43

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

Have you been exposed to someone with 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 (479c3cf623e593b0)', Time: '2021-03-18T10:49:31', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '95e8d46f-bc2b-4ac9-8513-1e17be7d91df'	System	18 Mar 2021 14:49:43
User entered 'No (N)'	System	18 Mar 2021 14:49:43

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2021-03-18T10:49:38', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '95e8d46f-bc2b-4ac9-8513-1e17be7d91df' User entered '18 Mar 2021 10:49:38'	System	18 Mar 2021 14:49:43

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[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 (479c3cf623e593b0)', Time: '2021-03-25T06:44:39', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '3147df85-a23b-4b89-b6e4-d274a54a54cb'	System	25 Mar 2021 10:44:50
User entered 'No (N)'	System	25 Mar 2021 10:44:50

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

Have you been exposed to someone with 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 (479c3cf623e593b0)', Time: '2021-03-25T06:44:42', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '3147df85-a23b-4b89-b6e4-d274a54a54cb'	System	25 Mar 2021 10:44:50
User entered 'No (N)'	System	25 Mar 2021 10:44:50

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2021-03-25T06:44:47', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '3147df85-a23b-4b89-b6e4-d274a54a54cb' User entered '25 Mar 2021 06:44:47'	System	25 Mar 2021 10:44:50
	System	25 Mar 2021 10:44:50

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[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 (479c3cf623e593b0)', Time: '2021-04-01T09:02:31', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'a15ede83-1302-4773-8142-b8c41e16ac26'	System	01 Apr 2021 13:03:43
User entered 'No (N)'	System	01 Apr 2021 13:03:43

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

Have you been exposed to someone with 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 (479c3cf623e593b0)', Time: '2021-04-01T09:02:40', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'a15ede83-1302-4773-8142-b8c41e16ac26'	System	01 Apr 2021 13:03:43
User entered 'No (N)'	System	01 Apr 2021 13:03:43

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2021-04-01T09:03:43', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'a15ede83-1302-4773-8142-b8c41e16ac26'	System	01 Apr 2021 13:03:43
User entered '01 Apr 2021 09:03:43'	System	01 Apr 2021 13:03:43

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[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 (479c3cf623e593b0)', Time: '2021-04-09T11:26:35', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'd98bfdd6-76b6-4a17-b674-bdfb89057984'	System	09 Apr 2021 15:26:48
User entered 'No (N)'	System	09 Apr 2021 15:26:48

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

Have you been exposed to someone with 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 (479c3cf623e593b0)', Time: '2021-04-09T11:26:40', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'd98bfdd6-76b6-4a17-b674-bdfb89057984'	System	09 Apr 2021 15:26:48
User entered 'No (N)'	System	09 Apr 2021 15:26:48

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2021-04-09T11:26:44', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'd98bfdd6-76b6-4a17-b674-bdfb89057984' User entered '09 Apr 2021 11:26:44'	System	09 Apr 2021 15:26:48
	System	09 Apr 2021 15:26:48

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[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 (479c3cf623e593b0)', Time: '2021-04-15T20:06:17', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'b6032b5c-266a-440a-9b1f-bb574cd15766'	System	16 Apr 2021 00:09:12
User entered 'No (N)'	System	16 Apr 2021 00:09:12

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

Have you been exposed to someone with 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 (479c3cf623e593b0)', Time: '2021-04-15T20:06:21', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'b6032b5c-266a-440a-9b1f-bb574cd15766'	System	16 Apr 2021 00:09:12
User entered 'No (N)'	System	16 Apr 2021 00:09:12

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2021-04-15T20:06:25', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: 'b6032b5c-266a-440a-9b1f-bb574cd15766'	System	16 Apr 2021 00:09:12
User entered '15 Apr 2021 20:06:25'	System	16 Apr 2021 00:09:12

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[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 (479c3cf623e593b0)', Time: '2021-04-22T06:58:06', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '1e85d681-2a82-42d1-9125-080fa272acfd'	System	22 Apr 2021 10:58:25
User entered 'No (N)'	System	22 Apr 2021 10:58:25

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

Have you been exposed to someone with 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 (479c3cf623e593b0)', Time: '2021-04-22T06:58:15', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '1e85d681-2a82-42d1-9125-080fa272acfd'	System	22 Apr 2021 10:58:25
User entered 'No (N)'	System	22 Apr 2021 10:58:25

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2021-04-22T06:58:21', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '1e85d681-2a82-42d1-9125-080fa272acfd'	System	22 Apr 2021 10:58:25
User entered '22 Apr 2021 06:58:21'	System	22 Apr 2021 10:58:25

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[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 (479c3cf623e593b0)', Time: '2021-04-29T11:47:56', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '2dcc69c8-9981-494e-8820-9e2fbed495d7'	System	29 Apr 2021 15:48:05
User entered 'No (N)'	System	29 Apr 2021 15:48:05

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

Have you been exposed to someone with 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 (479c3cf623e593b0)', Time: '2021-04-29T11:47:59', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '2dcc69c8-9981-494e-8820-9e2fbed495d7'	System	29 Apr 2021 15:48:05
User entered 'No (N)'	System	29 Apr 2021 15:48:05

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2021-04-29T11:48:03', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '2dcc69c8-9981-494e-8820-9e2fbed495d7'	System	29 Apr 2021 15:48:05
User entered '29 Apr 2021 11:48:03'	System	29 Apr 2021 15:48:05

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '03 Nov 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '07 Nov 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '10 Nov 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '14 Nov 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '17 Nov 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '21 Nov 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '24 Nov 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '28 Nov 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '01 Dec 2022 00:01'	System	20 Nov 2020 11:12:11

US3952173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:31:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:12:11
Amendment Manager: User entered '05 Dec 2022 23:59'	System	20 Nov 2020 11:12:11

US3952173

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:31:39

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 09:58:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2021-03-04T09:06:29', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '0fce7544-5c54-4b8d-b515-aba561451c92'	System	04 Mar 2021 14:06:35
User entered 'No (N)'	System	04 Mar 2021 14:06:35

US3952173

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:31:39

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:58:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (479c3cf623e593b0)', Time: '2021-03-04T09:06:32', User OID: 'PatientReportedOutcome (US3952173)', ODM File OID: '0fce7544-5c54-4b8d-b515-aba561451c92'	System	04 Mar 2021 14:06:35
User entered '04 Mar 2021 09:06:32'	System	04 Mar 2021 14:06:35

US3952173

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:49:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 23:39:22

US3952173

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:49:02
User entered '21 Dec 2020'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 23:39:22

US3952173

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:49:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 23:39:22

US3952173

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:49:02
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 23:39:22

US3952173

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:31:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:49:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 23:39:30

US3952173

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:31:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:14
User entered 'I'	System	21 Dec 2020 23:39:30

US3952173

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered 'Yes (Y)'	Stephanie Melton (b) (4)	25 Jan 2021 16:44:02

US3952173

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered '25 Jan 2021'	Stephanie Melton (b) (4)	25 Jan 2021 16:44:02

US3952173

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered 'Contact Made (CONTACT MADE)'	Stephanie Melton (b) (4)	25 Jan 2021 16:44:02

US3952173

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered empty.	Stephanie Melton (b) (4)	25 Jan 2021 16:44:02

US3952173

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:31:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered 'Yes (Y)'	Stephanie Melton (b) (4)	25 Jan 2021 16:44:06

US3952173

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:31:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:03
User entered 'I'	System	25 Jan 2021 16:44:06

US3952173

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered 'Yes (Y)'	(b) (4) Atanas Filev (b) (4)	25 Feb 2021 16:29:47

US3952173

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered '23 Feb 2021'	(b) (4) Atanas Filev (b) (4) (b) (4)	25 Feb 2021 16:29:47

US3952173

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Atanas Filev (b) (4) (b) (4)	25 Feb 2021 16:29:47

US3952173

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	25 Feb 2021 16:29:47

US3952173

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:31:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered 'Yes (Y)'	(b) (4) Atanas Filev (b) (4) (b) (4)	25 Feb 2021 16:29:50

US3952173

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:31:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:03
User entered 'I'	System	25 Feb 2021 16:29:50

US3952173

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:12:33

US3952173

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered '25 Mar 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:12:33

US3952173

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:12:33

US3952173

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:12:33

US3952173

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:31:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:12:38

US3952173

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:31:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:03
User entered 'I'	System	25 Mar 2021 14:12:38

US3952173

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

Form: Visit Date

Generated On: 10 Jun 2021 10:31:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	01 Mar 2021 21:49:31

US3952173

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

Form: Visit Date

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered '23 Feb 2021'	(b) (4) Nick Bart (b) (4)	01 Mar 2021 21:49:31

US3952173

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

Form: Visit Date

Generated On: 10 Jun 2021 10:31:39

[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 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered 'Clinic (Clinic)'	(b) (4) Nick Bart (b) (4)	01 Mar 2021 21:49:31

US3952173

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

Form: Visit Date

Generated On: 10 Jun 2021 10:31:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User entered 'UNBLND_DECIDE'	System	01 Mar 2021 21:49:31

US3952173

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

Form: Unblinding

Generated On: 10 Jun 2021 10:31:39

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered '23 Feb 2021'	(b) (4) Nick Bart (b) (4)	01 Mar 2021 21:49:51

US3952173

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

Form: Unblinding

Generated On: 10 Jun 2021 10:31:39

[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 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered '0'	(b) (4) Nick Bart (b) (4)	10 Mar 2021 18:56:53
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 20:07:12

US3952173

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

Form: Unblinding

Generated On: 10 Jun 2021 10:31:39

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	01 Mar 2021 21:49:51

US3952173

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

Form: Unblinding

Generated On: 10 Jun 2021 10:31:39

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4)	10 Mar 2021 18:56:53
Amendment Manager inserted this DataPoint.	Nick Bart (b) (4)	06 Mar 2021 20:07:12
	System	

US3952173

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

Form: Unblinding

Generated On: 10 Jun 2021 10:31:39

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered '23 Feb 2021'	(b) (4) Nick Bart (b) (4)	01 Mar 2021 21:49:51

US3952173

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

Form: Unblinding

Generated On: 10 Jun 2021 10:31:39

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered 'Placebo (Placebo)'	(b) (4) Nick Bart (b) (4)	01 Mar 2021 21:49:51

US3952173

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

Form: Unblinding

Generated On: 10 Jun 2021 10:31:39

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered 'Placebo (Placebo)'	(b) (4) Nick Bart (b) (4)	01 Mar 2021 21:49:51

US3952173

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

Form: Unblinding

Generated On: 10 Jun 2021 10:31:39

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered 'Placebo (Placebo)'	(b) (4) Nick Bart (b) (4)	01 Mar 2021 21:49:51

US3952173

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

Form: Unblinding

Generated On: 10 Jun 2021 10:31:39

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	01 Mar 2021 21:49:51

US3952173

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

Form: Unblinding

Generated On: 10 Jun 2021 10:31:39

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User entered '1'	System	01 Mar 2021 21:49:51

US3952173

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

Form: Unblinding

Generated On: 10 Jun 2021 10:31:39

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User entered 'I'	System	01 Mar 2021 21:49:51

US3952173

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:31:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	10 Mar 2021 18:58:25

US3952173

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:31:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	10 Mar 2021 18:58:25

US3952173

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:31:39

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User entered empty.	System	10 Mar 2021 18:58:25
DataPoint set to visible.	System	01 Mar 2021 21:49:51

US3952173

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:31:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	10 Mar 2021 18:58:25

US3952173

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:31:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	10 Mar 2021 18:58:25

US3952173

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User entered empty.	System	10 Mar 2021 18:58:25
DataPoint set to visible.	System	01 Mar 2021 21:49:51

US3952173

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User accepted default value 'Pre-Dose (PREDOSE)'	Nick Bart (b) (4)	10 Mar 2021 18:58:25

US3952173

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	10 Mar 2021 18:58:25

US3952173

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered '09 Mar 2021'	(b) (4) Nick Bart (b) (4)	10 Mar 2021 18:58:25

US3952173

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered '12:17'	(b) (4) Nick Bart (b) (4)	10 Mar 2021 18:58:25

US3952173

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User entered '09 Mar 2021 12:17'	System	10 Mar 2021 18:58:25

US3952173

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered '36.8' C	(b) (4) Nick Bart (b) (4)	10 Mar 2021 18:58:25

US3952173

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered 'Oral (Oral)'	(b) (4) Nick Bart (b) (4)	10 Mar 2021 18:58:25

US3952173

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered empty.	(b) (4) Nick Bart (b) (4)	10 Mar 2021 18:58:25

US3952173

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered '120'	(b) (4) Nick Bart (b) (4)	10 Mar 2021 18:58:25

US3952173

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User entered 'bpm'	System	10 Mar 2021 18:58:25

US3952173

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered '18'	(b) (4) Nick Bart (b) (4)	10 Mar 2021 18:58:25

US3952173

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User entered 'breaths/min'	System	10 Mar 2021 18:58:25

US3952173

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered '95'	(b) (4) Nick Bart (b) (4)	10 Mar 2021 18:58:25

US3952173

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User entered 'mmHg'	System	10 Mar 2021 18:58:25

US3952173

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered '79'	(b) (4) Nick Bart (b) (4)	10 Mar 2021 18:58:25

US3952173

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:31:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User entered 'mmHg'	System	10 Mar 2021 18:58:25

US3952173

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:31:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	10 Mar 2021 18:58:25

US3952173

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:31:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	10 Mar 2021 18:58:25

US3952173

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:31:39

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User entered empty.	System	10 Mar 2021 18:58:25
DataPoint set to visible.	System	01 Mar 2021 21:49:51

US3952173

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User accepted default value 'Post-Dose (POSTDOSE)'	Nick Bart (b) (4)	10 Mar 2021 18:58:25

US3952173

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	10 Mar 2021 18:58:25

US3952173

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered '09 Mar 2021'	(b) (4) Nick Bart (b) (4)	10 Mar 2021 18:58:25

US3952173

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered '13:34'	(b) (4) Nick Bart (b) (4)	10 Mar 2021 18:58:25

US3952173

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User entered '09 Mar 2021 13:34'	System	10 Mar 2021 18:58:25

US3952173

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered '100.0' F	(b) (4) Nick Bart (b) (4)	10 Mar 2021 18:58:25

US3952173

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered 'Oral (Oral)'	(b) (4) Nick Bart (b) (4)	10 Mar 2021 18:58:25

US3952173

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered empty.	(b) (4) Nick Bart (b) (4)	10 Mar 2021 18:58:25

US3952173

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered '121'	(b) (4) Nick Bart (b) (4)	10 Mar 2021 18:58:25

US3952173

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User entered 'bpm'	System	10 Mar 2021 18:58:25

US3952173

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered '14'	(b) (4) Nick Bart (b) (4)	10 Mar 2021 18:58:25

US3952173

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User entered 'breaths/min'	System	10 Mar 2021 18:58:25

US3952173

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered '108'	(b) (4) Nick Bart (b) (4)	10 Mar 2021 18:58:25

US3952173

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User entered 'mmHg'	System	10 Mar 2021 18:58:25

US3952173

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered '65'	(b) (4) Nick Bart (b) (4)	10 Mar 2021 18:58:25

US3952173

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:31:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User entered 'mmHg'	System	10 Mar 2021 18:58:25

US3952173

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

Form: Physical Examination

Generated On: 10 Jun 2021 10:31:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	10 Mar 2021 18:58:44

US3952173

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

Form: Physical Examination

Generated On: 10 Jun 2021 10:31:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered '09 Mar 2021'	(b) (4) Nick Bart (b) (4)	10 Mar 2021 18:58:44

US3952173

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

Form: Exposure

Generated On: 10 Jun 2021 10:31:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	10 Mar 2021 18:59:25

US3952173

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

Form: Exposure

Generated On: 10 Jun 2021 10:31:39

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered empty.	(b) (4) Nick Bart (b) (4)	10 Mar 2021 18:59:25

US3952173

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

Form: Exposure

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered empty.	Nick Bart (b) (4)	10 Mar 2021 18:59:25

US3952173

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

Form: Exposure

Generated On: 10 Jun 2021 10:31:39

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User entered 'mRNA-1273'	System	10 Mar 2021 18:59:25
DataPoint set to visible.	System	01 Mar 2021 21:49:51

US3952173

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

Form: Exposure

Generated On: 10 Jun 2021 10:31:39

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered '09 Mar 2021'	(b) (4) Nick Bart (b) (4)	10 Mar 2021 18:59:25

US3952173

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

Form: Exposure

Generated On: 10 Jun 2021 10:31:39

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered '12:57'	(b) (4) Nick Bart (b) (4)	10 Mar 2021 18:59:25

US3952173

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

Form: Exposure

Generated On: 10 Jun 2021 10:31:39

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User entered '09 Mar 2021 12:57'	System	10 Mar 2021 18:59:25

US3952173

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

Form: Exposure

Generated On: 10 Jun 2021 10:31:39

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered 'Left Arm (LEFT ARM)'	(b) (4) Nick Bart (b) (4)	10 Mar 2021 18:59:25

US3952173

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

Form: Exposure

Generated On: 10 Jun 2021 10:31:39

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User entered 'ONCE'	System	10 Mar 2021 18:59:25

US3952173

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

Form: Exposure

Generated On: 10 Jun 2021 10:31:39

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User entered 'INTRAMUSCULAR'	System	10 Mar 2021 18:59:25

US3952173

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:31:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	01 Mar 2021 21:50:02

US3952173

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:31:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered '23 Feb 2021'	(b) (4) Nick Bart (b) (4)	01 Mar 2021 21:50:02

US3952173

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:31:39

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered '12:27'	(b) (4) Nick Bart (b) (4)	01 Mar 2021 21:50:02

US3952173

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:31:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User entered '23 Feb 2021 12:27'	System	01 Mar 2021 21:50:02

US3952173

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:31:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	01 Mar 2021 21:50:12

US3952173

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered '23 Feb 2021'	(b) (4) Nick Bart (b) (4)	01 Mar 2021 21:50:12

US3952173

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:31:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered '12:30'	(b) (4) Nick Bart (b) (4)	01 Mar 2021 21:50:12

US3952173

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:31:39

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User entered '23 Feb 2021 12:30'	System	01 Mar 2021 21:50:12

US3952173

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

Form: Continuing

Generated On: 10 Jun 2021 10:31:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	01 Mar 2021 21:49:56

US3952173

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

Form: Continuing

Generated On: 10 Jun 2021 10:31:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:30
User entered 'I'	System	01 Mar 2021 21:49:56

US3952173

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:02:18
User entered 'No (N)'	Nick Bart (b) (4)	10 Mar 2021 19:00:28

US3952173

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered '16 Mar 2021' reason for change: Data Entry Error	(b) (4)	16 Mar 2021 19:02:18
User entered empty.	Nick Bart (b) (4)	10 Mar 2021 19:00:28

US3952173

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 19:02:18
User entered empty.	Nick Bart (b) (4)	10 Mar 2021 19:00:28

US3952173

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:31:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered empty.	(b) (4) Nick Bart (b) (4)	10 Mar 2021 19:00:28

US3952173

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:31:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	10 Mar 2021 19:00:34

US3952173

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:31:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:56
User entered 'I'	System	10 Mar 2021 19:00:34

US3952173

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:31:39

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:56
User entered 'I'	System	10 Mar 2021 19:00:34
DataPoint set to visible.	System	10 Mar 2021 19:00:34

US3952173

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:31:39

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
DataPoint set to visible.	System	10 Mar 2021 19:00:34

US3952173

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:31:39

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:46:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:40
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:13:14
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	07 Apr 2021 20:11:08
User entered 'No (N)'	Mimi Van Der Leden	07 Apr 2021 20:11:08
	(b) (4)	
	Nick Bart (b) (4)	10 Mar 2021 18:55:32

US3952173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:31:39

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 01:59:57
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:17
User entered 'USA-US215-2021-mRNA-1273-P301000007'	System	08 Apr 2021 13:19:59
User entered 'New'	(b) (4), (b) (6)	08 Apr 2021 13:19:59

US3952173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:31:39

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 01:59:59
User coded data point as SOC: Eye disorders, HLGT: Retina, choroid and vitreous haemorrhages and vascular disorders, HLT: Retinal bleeding and vascular disorders (excl retinopathy), PT: Retinal artery occlusion, LLT: Retinal artery occlusion - version MedDRA\\23.0.	Coder Import (b) (4)	08 Apr 2021 06:21:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	07 Apr 2021 20:18:20
User entered '(L) eye retinal artery occlusion'	Mimi Van Der Leden	07 Apr 2021 20:18:15
	(b) (4)	

US3952173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:31:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:00:00
User entered 'Yes (Y)'	Mimi Van Der Leden	07 Apr 2021 20:18:15
	(b) (4)	

US3952173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:31:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:00:03
User entered 'No (N)'	Mimi Van Der Leden	07 Apr 2021 20:18:15
	(b) (4)	

US3952173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:31:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:00:08
User entered 'No (N)'	Mimi Van Der Leden	07 Apr 2021 20:18:15
	(b) (4)	

US3952173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
User opened query 'PV Query: please confirm event start date of 24 Mar 2021 and date of hospital admission 29 Mar 2021. thank you! ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 17:52:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:00:09
User entered '24 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 17:45:01
User entered '29 Mar 2021'	Mimi Van Der Leden	07 Apr 2021 20:18:15
	(b) (4)	

US3952173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:31:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:00:11
User entered empty.	Mimi Van Der Leden	07 Apr 2021 20:18:15
	(b) (4)	

US3952173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:31:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 20:18:15

US3952173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:31:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:00:12
User entered 'No (N)'	Mimi Van Der Leden	07 Apr 2021 20:18:15
	(b) (4)	

US3952173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:31:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:00:14
User entered '31 Mar 2021'	Mimi Van Der Leden	07 Apr 2021 20:18:15
	(b) (4)	

US3952173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:31:39

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:00:18
User entered empty.	Mimi Van Der Leden	07 Apr 2021 20:18:15
	(b) (4)	

US3952173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:31:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 20:18:15

US3952173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:31:39

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:00:19
User entered 'Grade 3/Severe (Grade 3/Severe)'	Mimi Van Der Leden	07 Apr 2021 20:18:15
	(b) (4)	

US3952173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:31:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:00:21
User entered 'Yes (Y)'	Mimi Van Der Leden	07 Apr 2021 20:18:15
	(b) (4)	

US3952173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:31:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:00:23
User entered '0'	Mimi Van Der Leden	07 Apr 2021 20:18:15
	(b) (4)	

US3952173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:31:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:00:24
User entered '0'	Mimi Van Der Leden	07 Apr 2021 20:18:15
	(b) (4)	

US3952173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:31:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:00:26
User entered '1'	Mimi Van Der Leden	07 Apr 2021 20:18:15
	(b) (4)	

US3952173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:31:39

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:00:31
User entered '29 Mar 2021'	Mimi Van Der Leden	07 Apr 2021 20:18:15
	(b) (4)	

US3952173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:31:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 17:01:19
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:00:29
User entered '31 Mar 2021'	Mimi Van Der Leden (b) (4)	07 Apr 2021 20:18:15

US3952173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:31:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	07 Apr 2021 20:18:15
User entered 'Unknown (UNK)'	Mimi Van Der Leden (b) (4)	07 Apr 2021 20:18:15

US3952173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:31:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:00:34
User entered empty.	Mimi Van Der Leden	07 Apr 2021 20:18:15
	(b) (4)	

US3952173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:31:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:00:36
User entered '0'	Mimi Van Der Leden	07 Apr 2021 20:18:15
	(b) (4)	

US3952173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:31:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:00:37
User entered '0'	Mimi Van Der Leden	07 Apr 2021 20:18:15
	(b) (4)	

US3952173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:31:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:00:39
User entered '0'	Mimi Van Der Leden	07 Apr 2021 20:18:15
	(b) (4)	

US3952173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:31:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:00:40
User entered 'Not Related (NOT RELATED)'	Mimi Van Der Leden	07 Apr 2021 20:18:15
	(b) (4)	

US3952173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:31:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:00:43
User entered 'Not Related (NOT RELATED)'	Mimi Van Der Leden	07 Apr 2021 20:18:15
	(b) (4)	

US3952173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:31:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 09 Mar 2021, then event occurred). ' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:01:00
	(b) (4), (b) (6)	13 Apr 2021 02:00:45
User entered 'Not Applicable (NOT APPLICABLE)'	Mimi Van Der Leden	07 Apr 2021 20:18:15
	(b) (4)	

US3952173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:31:39

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:00:46
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	08 Apr 2021 17:45:01
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	07 Apr 2021 20:18:15
User entered '0'	Mimi Van Der Leden	07 Apr 2021 20:18:15
	(b) (4)	

US3952173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:31:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:00:48
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 17:45:01
User entered '0'	Mimi Van Der Leden (b) (4)	07 Apr 2021 20:18:15

US3952173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:31:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:00:50
User entered '0'	Mimi Van Der Leden	07 Apr 2021 20:18:15
	(b) (4)	

US3952173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:31:39

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:00:52
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mimi Van Der Leden	07 Apr 2021 20:18:15
	(b) (4)	

US3952173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:31:39

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:00:53
User entered empty.	Mimi Van Der Leden	07 Apr 2021 20:18:15
	(b) (4)	

US3952173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:31:39

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 17:01:29
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 17:01:09
User opened query 'PV Query: Please clarify dates for "left leg surgery"; start date listed as Jun 2000, end date listed as Sep 2000- did subject have multiple procedures? ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 17:00:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:00:55
User entered 'Subject admitted to hospital on 29 Mar2021 with blurred (L) vision. Diagnosed with (L) retinal artery occlusion. PMH - hypertension Discharged from hospital on 31Mar20121on medication that subject will provide details on. Medical records have been requested and update will be provided upon receipt and review.'	Mimi Van Der Leden (b) (4)	07 Apr 2021 20:18:15

US3952173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:31:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Apr 2021 20:18:15

US3952173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:31:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Apr 2021 20:18:15

US3952173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:31:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Apr 2021 20:18:15

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:26:41
User entered 'USA-US215-2021-mRNA-1273-P301000008'	System	13 Apr 2021 17:26:36
User entered 'New'	(b) (4), (b) (6)	13 Apr 2021 17:26:36

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Crystal arthropathic disorders, PT: Chondrocalcinosis pyrophosphate, LLT: Pseudogout - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Apr 2021 18:35:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Apr 2021 18:35:55
Data point term sent to Coder	System	25 Apr 2021 15:34:24
Query 'For coding purposes, please split OLIGOARTHRITIS SECONDARY TO PSEUDOGOUT FLARE into separate entries. 1. OLIGOARTHRITIS [SECONDARY TO PSEUDOGOUT FLARE] and 2. Pseudogout Flare' canceled (Site from System).	Coder Import (b) (4) (b) (4)	25 Apr 2021 15:33:57
User opened query 'For coding purposes, please split OLIGOARTHRITIS SECONDARY TO PSEUDOGOUT FLARE into separate entries. 1. OLIGOARTHRITIS [SECONDARY TO PSEUDOGOUT FLARE] and 2. Pseudogout Flare' (Site from System).	Coder Import (b) (4) (b) (4)	25 Apr 2021 12:29:41
Data point term sent to Coder	System	19 Apr 2021 19:46:18
Coding entries removed.	Mimi Van Der Leden (b) (4)	19 Apr 2021 19:46:00
User entered 'Oligoarthritis secondary to Pseudogout Flare' reason for change: New Information	Mimi Van Der Leden (b) (4)	19 Apr 2021 19:46:00
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Joint swelling, LLT: Knee swelling - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 12:33:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 12:33:01
Data point term sent to Coder	System	12 Apr 2021 16:02:47
User entered '(L) knee swelling'	Mimi Van Der Leden (b) (4)	12 Apr 2021 16:02:10

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mimi Van Der Leden (b) (4)	12 Apr 2021 16:02:10

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mimi Van Der Leden (b) (4)	12 Apr 2021 16:02:10

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mimi Van Der Leden (b) (4)	12 Apr 2021 16:02:10

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
User entered '08 Apr 2021' reason for change: Data Entry Error	Nick Bart (b) (4)	12 Apr 2021 18:16:54
User entered '8 Apr 2021'	Mimi Van Der Leden (b) (4)	12 Apr 2021 16:02:10

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Mimi Van Der Leden (b) (4)	12 Apr 2021 16:02:10

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:02:10

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

[Ongoing?](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 13:08:13
User entered 'Yes (Y)'	Mimi Van Der Leden (b) (4)	12 Apr 2021 16:02:10

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Mimi Van Der Leden (b) (4)	12 Apr 2021 16:02:10

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Mimi Van Der Leden (b) (4)	12 Apr 2021 16:02:10

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 20:20:36
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 13:07:55
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' canceled (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 13:07:50
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 13:07:40
User entered empty.	System	12 Apr 2021 16:02:10

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	Mimi Van Der Leden (b) (4)	12 Apr 2021 16:02:10

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mimi Van Der Leden (b) (4)	12 Apr 2021 16:02:10

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Mimi Van Der Leden (b) (4)	12 Apr 2021 16:02:10

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Mimi Van Der Leden (b) (4)	12 Apr 2021 16:02:10

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	14 Apr 2021 07:44:29
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Pending medical records.' (Site from System).	(b) (4), (b) (6)	12 Apr 2021 18:25:43
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	12 Apr 2021 16:02:10
User entered 'I'	Mimi Van Der Leden (b) (4)	12 Apr 2021 16:02:10

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '09 Apr 2021' reason for change: Data Entry Error	Nick Bart (b) (4)	12 Apr 2021 18:16:33
User entered '9 Apr 2021'	Mimi Van Der Leden (b) (4)	12 Apr 2021 16:02:10

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please leave this query open until 'Hospital Discharge date' become available. Thank you' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 13:08:59
Query 'Per CDM: Please leave this query open until 'Hospital Discharge date' become available. Thank you' answered with 'updated' (Site from DM).	Mimi Van Der Leden (b) (4)	19 Apr 2021 19:48:05
User entered '12 Apr 2021' reason for change: New Information	Mimi Van Der Leden (b) (4)	19 Apr 2021 19:46:00
User opened query 'Per CDM: Please leave this query open until 'Hospital Discharge date' become available. Thank you' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 07:48:45
User entered empty.	Mimi Van Der Leden (b) (4)	12 Apr 2021 16:02:10

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mimi Van Der Leden (b) (4)	12 Apr 2021 16:02:10

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Mimi Van Der Leden (b) (4)	12 Apr 2021 16:02:10

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Mimi Van Der Leden (b) (4)	12 Apr 2021 16:02:10

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Mimi Van Der Leden (b) (4)	12 Apr 2021 16:02:10

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Mimi Van Der Leden (b) (4)	12 Apr 2021 16:02:10

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Mimi Van Der Leden (b) (4)	12 Apr 2021 16:02:10

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Mimi Van Der Leden (b) (4)	12 Apr 2021 16:02:10

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Mimi Van Der Leden (b) (4)	12 Apr 2021 16:02:10

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

[None](#)

Audit	User	Time (GMT)
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	12 Apr 2021 18:20:18
User entered '1' reason for change: Data Entry Error	Nick Bart (b) (4)	12 Apr 2021 18:20:18
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	12 Apr 2021 16:02:10
User entered '0'	Mimi Van Der Leden (b) (4)	12 Apr 2021 16:02:10

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Mimi Van Der Leden (b) (4)	12 Apr 2021 16:02:10

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Mimi Van Der Leden (b) (4)	12 Apr 2021 16:02:10

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mimi Van Der Leden (b) (4)	12 Apr 2021 16:02:10

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Mimi Van Der Leden (b) (4)	12 Apr 2021 16:02:10

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on, then event occurred). ' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 13:08:42
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. [mRNA-1273 protocols where subject was hospitalization during study participation] ' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 13:08:35
User opened query 'PV Query: Please add treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). ' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 13:08:25

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT ADMITTED TO HOSPITAL WITH (L) KNEE SWELLING ON 09APR2021. STATES THAT SYMPTOMS BEGAN 08APR2021 EVENING. COULD NOT BEAR WEIGHT AND WAS ADMITTED TO HOSPITAL. HAS HAD KNEE DRAINED. CURRENTLY REPORTS THAT (R) KNEE IS NOW SWOLLEN. SUBJECT UNCERTAIN OF DIAGNOSIS. FURTHER INFORMATION WILL BE PROVIDED UPON RECEIPT OF MEDICAL RECORDS UPON DISCHARGE. Medical Records received and reviewed. Admit Date 09Apr2021 Symptom onset 08Apr2021 Discharge date 12Apr2021 Clarification - Subject admitted with (R) knee swelling (not Left as he described). In hospital developed (L) knee swelling as well. Subject with hx of pseudogout, was admitted for concerns of septic arthritis vs pseudogout flare given his (R) knee swelling and pain for one day. During his hospitalization, his (R) knee swelling and pain decreased significantly after receiving colchicine, vancomycin, ceftriaxone and ibuprofen. His hospital course was complicated by the development of L knee pain and swelling on 11Apr2021 that resolved on 12Apr2021. Given his history of pseudogout, involvement of more than one joint, the lack of growth on blood and synovial fluid cultures for 3 days, and the lack of organisms reported in synovial fluid, this was most likely a pseudogout flare that has resolved. Rheumatology and ortho consults during his hospital stay. Procedures - arthrocentesis with SBC 77, 93% PMNs, no organisms. Received vancomycin x2dys and ceftriaxone x1 dy for possible septic arthritis. Meds stopped when unlikely dx of septic arthritis. Xray of (R) knee - 09Apr2021 - moderate sized suprapatellar joint effusion with advanced osteoarthritis Chest Xray - 09Apr2021 - OA (B) shoulders with mild cardiomegaly CTA - chest - mild emphysema, stable nodules Both (R)	Mimi Van Der Leden (b) (4)	19 Apr 2021 19:46:00

PRODUCTION RELEASE (v12.003
EAB) (1725)

1675 of 1797

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

[Narrative](#)

Audit	User	Time (GMT)
and (L) knee swelling/pain resolved with colchicine and ibuprofen. Patient discharged home on 12APR2021 with plan to continue colchicine.' reason for change: New Information User entered 'Subject admitted to hospital with (L) knee swelling on 09APR2021. States that symptoms began 08APR2021 evening. Could not bear weight and was admitted to hospital. Has had knee drained. Currently reports that (R) knee is now swollen. Subject uncertain of diagnosis. Further information will be provided upon receipt of Medical Records upon discharge'	Mimi Van Der Leden (b) (4)	12 Apr 2021 16:02:10

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 16:02:10

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 16:02:10

US3952173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:31:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Apr 2021 16:02:10

US3952173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:46:24
User closed query 'Per ETRTR: According to SAE page "(L) EYE RETINAL ARTERY OCCLUSION", medication was given for SAE, but the same is missing in this folder. Please add Medications dosing details for SAE or reconcile otherwise, thanks.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 01:56:51
Query 'Per ETRTR: According to SAE page "(L) EYE RETINAL ARTERY OCCLUSION", medication was given for SAE, but the same is missing in this folder. Please add Medications dosing details for SAE or reconcile otherwise, thanks.' answered with 'Pending medical records' (Site from CRA).	Nick Bart (b) (4)	12 Apr 2021 18:20:56
User opened query 'Per ETRTR: According to SAE page "(L) EYE RETINAL ARTERY OCCLUSION", medication was given for SAE, but the same is missing in this folder. Please add Medications dosing details for SAE or reconcile otherwise, thanks.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 17:55:48
User signature succeeded.	Mimi Van Der Leden (b) (4)	08 Apr 2021 20:31:56
User entered 'Yes (Y)'	Nick Bart (b) (4)	05 Oct 2020 14:39:48

US3952173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:31:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE BESILATE, PRODUCTSYNONYM: AMLODIPINE BESYLATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Oct 2020 14:42:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 14:42:25
Data point term sent to Coder	System	05 Oct 2020 14:40:57
User entered 'amlodipine besylate'	Nick Bart (b) (4) (b) (4)	05 Oct 2020 14:40:17

US3952173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:31:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	05 Oct 2020 14:40:17

US3952173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:31:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
User entered 'hypertension'	Nick Bart (b) (4)	05 Oct 2020 14:40:17

US3952173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:31:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
User entered '5'	Nick Bart (b) (4)	05 Oct 2020 14:40:17

US3952173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:31:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
User entered 'mg (mg)'	Nick Bart (b) (4)	05 Oct 2020 14:40:17

US3952173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:31:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	05 Oct 2020 14:40:17

US3952173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:31:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered 'once daily (QD)'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 14:40:17

US3952173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:31:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	05 Oct 2020 14:40:17

US3952173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:31:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	05 Oct 2020 14:40:17

US3952173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:31:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	05 Oct 2020 14:40:17

US3952173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:31:39

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

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
User entered 'un UNK 2015'	Nick Bart (b) (4)	05 Oct 2020 14:40:17

US3952173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:31:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	05 Oct 2020 14:40:17

US3952173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:31:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
User entered 'Yes (Y)'	Nick Bart (b) (4)	05 Oct 2020 14:40:17

US3952173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:31:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	05 Oct 2020 14:40:17

US3952173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:31:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	05 Oct 2020 14:40:17

US3952173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:31:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 14:40:17

US3952173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:31:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 14:40:17

US3952173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:31:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 14:40:17

US3952173

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:31:39

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	10 Mar 2021 18:56:19

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:30
User entered	System	08 Apr 2021 13:19:59
'USA-US215-2021-MRNA-1273-P301000007'		

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:30
User entered 'Yes (Y)'	System	08 Apr 2021 13:19:59

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:30
User entered 'No (N)'	System	08 Apr 2021 13:19:59

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:30
User entered 'No (N)'	System	08 Apr 2021 13:19:59

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:30
User entered 'Yes (Y)'	System	08 Apr 2021 13:19:59

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:30
User entered 'No (N)'	System	08 Apr 2021 13:19:59

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:30
User entered 'No (N)'	System	08 Apr 2021 13:19:59

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:30
User entered 'No (N)'	System	08 Apr 2021 13:19:59

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:30
User entered 'Mimi'	System	08 Apr 2021 13:19:59

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:30
User entered 'Van Der Leden'	System	08 Apr 2021 13:19:59

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:30
User entered '15201 Shady Grove Dr'	System	08 Apr 2021 13:19:59

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:30
User entered 'Rockville'	System	08 Apr 2021 13:19:59

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:30
User entered '20850'	System	08 Apr 2021 13:19:59

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 13:18:25
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered 'US'	(b) (4) System	08 Apr 2021 13:20:37

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	09 Apr 2021 13:18:36
User entered '1'	System	08 Apr 2021 13:20:37

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:30
User entered	System	08 Apr 2021 13:19:59
'USA-US215-2021-MRNA-1273-P301000007'		

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:30
User entered 'Yes (Y)'	System	08 Apr 2021 13:19:59

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:30
User entered 'No (N)'	System	08 Apr 2021 13:19:59

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:30
User entered 'No (N)'	System	08 Apr 2021 13:19:59

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:30
User entered 'Yes (Y)'	System	08 Apr 2021 13:19:59

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:30
User entered 'No (N)'	System	08 Apr 2021 13:19:59

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:30
User entered 'No (N)'	System	08 Apr 2021 13:19:59

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:30
User entered 'No (N)'	System	08 Apr 2021 13:19:59

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:30
User entered 'Mimi'	System	08 Apr 2021 13:19:59

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:30
User entered 'Van Der Leden'	System	08 Apr 2021 13:19:59

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:30
User entered '15201 Shady Grove Dr'	System	08 Apr 2021 13:19:59

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:30
User entered 'Rockville'	System	08 Apr 2021 13:19:59

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:30
User entered '20850'	System	08 Apr 2021 13:19:59

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 13:18:25
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered 'US'	(b) (4) System	08 Apr 2021 13:20:37

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	09 Apr 2021 13:18:36
User entered '1'	System	08 Apr 2021 13:20:37

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:31:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
User entered '08/Apr/2021 06:20'	System	08 Apr 2021 13:20:37

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:31:39

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)	13 Apr 2021 02:01:05
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 13:18:25
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered 'I'	(b) (4), (b) (6)	08 Apr 2021 13:20:37

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:30
User entered	System	08 Apr 2021 13:19:59
'USA-US215-2021-MRNA-1273-P301000007'		

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:30
User entered 'Yes (Y)'	System	08 Apr 2021 13:19:59

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:30
User entered 'No (N)'	System	08 Apr 2021 13:19:59

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:30
User entered 'No (N)'	System	08 Apr 2021 13:19:59

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:30
User entered 'Yes (Y)'	System	08 Apr 2021 13:19:59

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:30
User entered 'No (N)'	System	08 Apr 2021 13:19:59

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:30
User entered 'No (N)'	System	08 Apr 2021 13:19:59

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:30
User entered 'No (N)'	System	08 Apr 2021 13:19:59

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:30
User entered 'Mimi'	System	08 Apr 2021 13:19:59

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:30
User entered 'Van Der Leden'	System	08 Apr 2021 13:19:59

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:30
User entered '15201 Shady Grove Dr'	System	08 Apr 2021 13:19:59

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:30
User entered 'Rockville'	System	08 Apr 2021 13:19:59

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:20:30
User entered '20850'	System	08 Apr 2021 13:19:59

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 13:18:25
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:31:56
User entered 'US'	(b) (4) System	08 Apr 2021 13:20:37

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	09 Apr 2021 13:18:36
User entered '1'	System	08 Apr 2021 13:20:37

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:31:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:47
	(b) (4)	
User entered '09/Apr/2021 08:18'	System	09 Apr 2021 13:18:36

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:31:39

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)	13 Apr 2021 02:01:05
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:47
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	09 Apr 2021 13:18:36

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:27:15
User entered		
'USA-US215-2021-MRNA-1273-P301000008'	System	13 Apr 2021 17:26:36

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
Reviewed for Safety.	(b) (4)	13 Apr 2021 17:27:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Apr 2021 17:26:36
	System	

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:27:15
User entered 'No (N)'	System	13 Apr 2021 17:26:36

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:27:15
User entered 'No (N)'	System	13 Apr 2021 17:26:36

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:27:15
User entered 'Yes (Y)'	System	13 Apr 2021 17:26:36

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:27:15
User entered 'No (N)'	System	13 Apr 2021 17:26:36

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:27:15
User entered 'No (N)'	System	13 Apr 2021 17:26:36

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:27:15
User entered 'No (N)'	System	13 Apr 2021 17:26:36

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:27:15
User entered 'Mimi'	System	13 Apr 2021 17:26:36

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:27:15
User entered 'Van Der Leden'	System	13 Apr 2021 17:26:36

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:27:15
User entered '15201 Shady Grove Dr'	System	13 Apr 2021 17:26:36

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:27:15
User entered 'Rockville'	System	13 Apr 2021 17:26:36

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
Reviewed for Safety.	(b) (4)	13 Apr 2021 17:27:15
User entered '20850'	(b) (4), (b) (6)	13 Apr 2021 17:26:36
	System	

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 13:34:21
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
User entered 'US'	(b) (4) System	13 Apr 2021 17:27:24

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Apr 2021 13:34:35
User entered '1'	System	13 Apr 2021 17:27:24

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:27:15
User entered		
'USA-US215-2021-MRNA-1273-P301000008'	System	13 Apr 2021 17:26:36

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
Reviewed for Safety.	(b) (4)	13 Apr 2021 17:27:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Apr 2021 17:26:36
	System	

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:27:15
User entered 'No (N)'	System	13 Apr 2021 17:26:36

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:27:15
User entered 'No (N)'	System	13 Apr 2021 17:26:36

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:27:15
User entered 'Yes (Y)'	System	13 Apr 2021 17:26:36

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:27:15
User entered 'No (N)'	System	13 Apr 2021 17:26:36

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:27:15
User entered 'No (N)'	System	13 Apr 2021 17:26:36

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:27:15
User entered 'No (N)'	System	13 Apr 2021 17:26:36

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:27:15
User entered 'Mimi'	System	13 Apr 2021 17:26:36

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:27:15
User entered 'Van Der Leden'	System	13 Apr 2021 17:26:36

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:27:15
User entered '15201 Shady Grove Dr'	System	13 Apr 2021 17:26:36

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:27:15
User entered 'Rockville'	System	13 Apr 2021 17:26:36

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:27:15
User entered '20850'	System	13 Apr 2021 17:26:36

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 13:34:21
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
User entered 'US'	(b) (4) System	13 Apr 2021 17:27:24

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Apr 2021 13:34:35
User entered '1'	System	13 Apr 2021 17:27:24

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:31:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
User entered '13/Apr/2021 12:27'	(b) (4) System	13 Apr 2021 17:27:24

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:31:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 13:34:21
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
User entered 'I'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:27:24

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:27:15
User entered 'USA-US215-2021-MRNA-1273-P301000008'	System	13 Apr 2021 17:26:36

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
Reviewed for Safety.	(b) (4)	13 Apr 2021 17:27:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Apr 2021 17:26:36
	System	

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:27:15
User entered 'No (N)'	System	13 Apr 2021 17:26:36

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:27:15
User entered 'No (N)'	System	13 Apr 2021 17:26:36

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
Reviewed for Safety.	(b) (4)	13 Apr 2021 17:27:15
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	13 Apr 2021 17:26:36

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:27:15
User entered 'No (N)'	System	13 Apr 2021 17:26:36

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:27:15
User entered 'No (N)'	System	13 Apr 2021 17:26:36

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:27:15
User entered 'No (N)'	System	13 Apr 2021 17:26:36

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:27:15
User entered 'Mimi'	System	13 Apr 2021 17:26:36

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:27:15
User entered 'Van Der Leden'	System	13 Apr 2021 17:26:36

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:27:15
User entered '15201 Shady Grove Dr'	System	13 Apr 2021 17:26:36

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:27:15
User entered 'Rockville'	System	13 Apr 2021 17:26:36

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:27:15
User entered '20850'	System	13 Apr 2021 17:26:36

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 13:34:21
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:04
User entered 'US'	(b) (4) System	13 Apr 2021 17:27:24

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:31:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Apr 2021 13:34:35
User entered '1'	System	13 Apr 2021 17:27:24

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:31:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	22 Apr 2021 16:05:49
User entered '20/Apr/2021 13:34'	(b) (4) System	20 Apr 2021 13:34:35

US3952173

Folder: SAE USA-US215-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:31:39

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.	Mimi Van Der Leden	22 Apr 2021 16:05:49
User entered 'I'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:34:35