

US3642333 (Prod: University of California San Diego)

Generated By: KC Joubran

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US3642333

Form: Participant Creation

Data signed: (b) (4) 13 Feb 2021 19:37:58

Generated On: 10 Jun 2021 09:18:10

Participant ID

US3642333

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

US3642333

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 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	SCRN

US3642333

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

Date of Birth (MMM yyyy)	(b) (6) 1947
Age	72
Age Units	YEARS
Age (Derived)	73
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

Date of Informed Consent (<i>dd MMM yyyy</i>)	21 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input checked="" type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 19:37:59

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 19:37:59

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Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 19:37:59

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Condition	TYPE 2 DIABETES
Start date (dd MMM yyyy)	UN MAY 2000
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)	MAY 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	21 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	13:26 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 13:26
Height (<i>xxx.x</i>)	176 cm
Weight (<i>xxx.x</i>)	82.7 kg
BMI (<i>xxx.x</i>)	26.69809 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 OCT 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 19:37:59

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 19:37:59

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

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

Visit date (dd MMM yyyy)	21 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

What was the date of randomization? (dd MMM yyyy) 21 OCT 2020

What was the participant's randomization number? 191544

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

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)	21 OCT 2020
Time of assessment (00:00-23:59)	13:26 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 13:26
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

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)	21 OCT 2020
Time of assessment (00:00-23:59)	15:35 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 15:35
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

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) 21 OCT 2020

What was the treatment time? (00:00-23:59) 14:54 (24 HR)

Treatment Date and Time (derived) 21 OCT 2020 14:54

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 OCT 2020
Collection time (00:00-23:59)	14:02 (24 HR)
Collection date and time (derived)	21 OCT 2020 14:02

US3642333

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

Collection date (dd MMM yyyy)			21 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:07	21 OCT 2020 14:07
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

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

97.3 °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

21 OCT 2020 15:25

PC Open Date & Time

21 OCT 2020 15:14

PC Close Date & Time

21 OCT 2020 17:44

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

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	21 OCT 2020 20:02
PC Open Date & Time	21 OCT 2020 18:39
PC Close Date & Time	22 OCT 2020 11:59

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:18:10

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

96.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 OCT 2020 20:02

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 OCT 2020 20:13

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.6 °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

24 OCT 2020 20:06

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:18:10

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

96.6 °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

25 OCT 2020 20:01

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

26 OCT 2020 20:10

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:18:10

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 OCT 2020 20:09

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

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

21 OCT 2020 15:26

PC Open Date & Time

21 OCT 2020 15:14

PC Close Date & Time

21 OCT 2020 17:44

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

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

21 OCT 2020 20:05

PC Open Date & Time

21 OCT 2020 18:39

PC Close Date & Time

22 OCT 2020 11:59

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:18:10

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

22 OCT 2020 20:02

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:18:10

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

23 OCT 2020 20:13

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:18:10

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

24 OCT 2020 20:07

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:18:10

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

25 OCT 2020 20:01

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:18:10

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

26 OCT 2020 20:10

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:18:10

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

27 OCT 2020 20:09

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

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 ☐

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

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

No ☒

Yes ☐

PC Time stamp	21 OCT 2020 15:27
PC Open Date & Time	21 OCT 2020 15:14
PC Close Date & Time	21 OCT 2020 17:44

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

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 ☐

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

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

No ☒

Yes ☐

PC Time stamp	21 OCT 2020 20:04
PC Open Date & Time	21 OCT 2020 18:39
PC Close Date & Time	22 OCT 2020 11:59

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:10

Yes <input type="checkbox"/>	
PC Time stamp	22 OCT 2020 20:03
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:10

Yes <input type="checkbox"/>	
PC Time stamp	23 OCT 2020 20:14
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:10

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 ☒

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:10

Yes <input type="checkbox"/>	
PC Time stamp	24 OCT 2020 20:07
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:10

Yes <input type="checkbox"/>	
PC Time stamp	25 OCT 2020 20:02
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:10

		Yes <input type="checkbox"/>
PC Time stamp	26 OCT 2020 20:10	
PC Open Date & Time	26 OCT 2020 12:00	
PC Close Date & Time	27 OCT 2020 11:59	

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:10

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

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EAB) (1725)

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:10

Yes <input type="checkbox"/>	
PC Time stamp	27 OCT 2020 20:10
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3642333

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642333

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642333

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642333

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642333

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

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

US3642333

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642333

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

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

Visit date (dd MMM yyyy)	18 NOV 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3642333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

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)	18 NOV 2020
Time of assessment (00:00-23:59)	13:15 (24 HR)
Vital Signs Date and Time (derived)	18 NOV 2020 13:15
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3642333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

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)	18 NOV 2020
Time of assessment (00:00-23:59)	15:15 (24 HR)
Vital Signs Date and Time (derived)	18 NOV 2020 15:15
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3642333

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 NOV 2020

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

US3642333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

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) 18 NOV 2020

What was the treatment time? (00:00-23:59) 14:40 (24 HR)

Treatment Date and Time (derived) 18 NOV 2020 14:40

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

US3642333

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 NOV 2020

Collection time (00:00-23:59)

13:45 (24 HR)

Collection date and time (derived)

18 NOV 2020 13:45

US3642333

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

Collection date (dd MMM yyyy)			18 NOV 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:30	18 NOV 2020 13:30
Nasopharyngeal Swab 2	No		

US3642333

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 NOV 2020 15:08

PC Open Date & Time

18 NOV 2020 15:00

PC Close Date & Time

18 NOV 2020 17:30

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

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

95.5 °F

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

Yes ☐
No ☒

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

PC Time Stamp	18 NOV 2020 19:08
PC Open Date & Time	18 NOV 2020 18:25
PC Close Date & Time	19 NOV 2020 11:59

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:18:10

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

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 NOV 2020 18:19

PC Open Date & Time

19 NOV 2020 12:00

PC Close Date & Time

20 NOV 2020 11:59

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:18:10

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

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 NOV 2020 18:08

PC Open Date & Time

20 NOV 2020 12:00

PC Close Date & Time

21 NOV 2020 11:59

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 NOV 2020 18:16

PC Open Date & Time

21 NOV 2020 12:00

PC Close Date & Time

22 NOV 2020 11:59

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:18:10

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

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 NOV 2020 19:19

PC Open Date & Time

22 NOV 2020 12:00

PC Close Date & Time

23 NOV 2020 11:59

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

23 NOV 2020 12:00

PC Close Date & Time

24 NOV 2020 11:59

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 NOV 2020 19:15

PC Open Date & Time

24 NOV 2020 12:00

PC Close Date & Time

25 NOV 2020 11:59

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

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

18 NOV 2020 15:06

PC Open Date & Time

18 NOV 2020 15:00

PC Close Date & Time

18 NOV 2020 17:30

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

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

18 NOV 2020 19:09

PC Open Date & Time

18 NOV 2020 18:25

PC Close Date & Time

19 NOV 2020 11:59

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:18:10

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

19 NOV 2020 18:19

PC Open Date & Time

19 NOV 2020 12:00

PC Close Date & Time

20 NOV 2020 11:59

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:18:10

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

20 NOV 2020 18:09

PC Open Date & Time

20 NOV 2020 12:00

PC Close Date & Time

21 NOV 2020 11:59

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:18:10

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

21 NOV 2020 18:17

PC Open Date & Time

21 NOV 2020 12:00

PC Close Date & Time

22 NOV 2020 11:59

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:18:10

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

22 NOV 2020 19:19

PC Open Date & Time

22 NOV 2020 12:00

PC Close Date & Time

23 NOV 2020 11:59

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

23 NOV 2020 12:00

PC Close Date & Time

24 NOV 2020 11:59

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:18:10

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

24 NOV 2020 19:24

PC Open Date & Time

24 NOV 2020 12:00

PC Close Date & Time

25 NOV 2020 11:59

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

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 ☐

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

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

No ☐

Yes ☒

PC Time stamp	18 NOV 2020 15:07
PC Open Date & Time	18 NOV 2020 15:00
PC Close Date & Time	18 NOV 2020 17:30

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

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 ☐

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

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

No ☐

Yes ☒

PC Time stamp	18 NOV 2020 19:09
PC Open Date & Time	18 NOV 2020 18:25
PC Close Date & Time	19 NOV 2020 11:59

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:10

Yes <input type="checkbox"/>	
PC Time stamp	19 NOV 2020 18:20
PC Open Date & Time	19 NOV 2020 12:00
PC Close Date & Time	20 NOV 2020 11:59

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:10

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

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EAB) (1725)

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:10

Yes <input type="checkbox"/>	
PC Time stamp	20 NOV 2020 18:09
PC Open Date & Time	20 NOV 2020 12:00
PC Close Date & Time	21 NOV 2020 11:59

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:10

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 ☒

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:10

Yes <input type="checkbox"/>	
PC Time stamp	21 NOV 2020 18:17
PC Open Date & Time	21 NOV 2020 12:00
PC Close Date & Time	22 NOV 2020 11:59

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:10

Yes <input type="checkbox"/>	
PC Time stamp	22 NOV 2020 19:20
PC Open Date & Time	22 NOV 2020 12:00
PC Close Date & Time	23 NOV 2020 11:59

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:10

Yes ☐

PC Time stamp

PC Open Date & Time

23 NOV 2020 12:00

PC Close Date & Time

24 NOV 2020 11:59

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:10

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 ☒

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:10

Yes <input type="checkbox"/>	
PC Time stamp	24 NOV 2020 19:26
PC Open Date & Time	24 NOV 2020 12:00
PC Close Date & Time	25 NOV 2020 11:59

US3642333

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642333

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642333

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642333

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642333

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642333

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642333

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 19:38:23

Generated On: 10 Jun 2021 09:18:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 DEC 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

US3642333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 19:38:23

Generated On: 10 Jun 2021 09:18:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 DEC 2020
Time of assessment (00:00-23:59)	13:17 (24 HR)
Vital Signs Date and Time (derived)	16 DEC 2020 13:17
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3642333

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 19:38:23

Generated On: 10 Jun 2021 09:18:10

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.

US3642333

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 DEC 2020

Collection time (00:00-23:59)

13:36 (24 HR)

Collection date and time (derived)

16 DEC 2020 13:36

US3642333

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

Date and time of submission	
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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 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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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 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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

01 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2021 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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 <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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Close Date & Time](#)

12 JAN 2021 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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 <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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

15 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2021 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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 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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

Patient Cloud Open Date & Time	22 JAN 2021 00:01
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Patient Cloud Close Date & Time	26 JAN 2021 23:59
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US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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 <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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

29 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2021 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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 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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

Patient Cloud Open Date & Time	05 FEB 2021 00:01
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Patient Cloud Close Date & Time	09 FEB 2021 23:59
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US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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 <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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

12 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2021 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

19 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2021 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

26 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2021 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

05 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2021 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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 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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

12 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2021 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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 <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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2021 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

26 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2021 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

02 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2021 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Close Date & Time](#)

13 APR 2021 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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 <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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

23 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2021 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

30 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

DAY 208

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

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

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

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

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

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

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

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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 <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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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="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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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 ☐

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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 ☐

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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="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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

Patient Cloud Open Date & Time	13 AUG 2021 00:01
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Patient Cloud Close Date & Time	17 AUG 2021 23:59
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US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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="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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

Date and time of submission

Patient Cloud Open Date & Time	20 AUG 2021 00:01
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Patient Cloud Close Date & Time	24 AUG 2021 23:59
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US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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 <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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

Patient Cloud Open Date & Time	27 AUG 2021 00:01
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Patient Cloud Close Date & Time	31 AUG 2021 23:59
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US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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 <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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 OCT 2021 00:01
Patient Cloud Close Date & Time	19 OCT 2021 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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 <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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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 ☐

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 NOV 2021 00:01
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Patient Cloud Close Date & Time	16 NOV 2021 23:59
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US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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 ☐

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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 <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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

DAY 439

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

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

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

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

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

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

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

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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 ☐

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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="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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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="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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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 ☐

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 FEB 2022 00:01
Patient Cloud Close Date & Time	22 FEB 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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 ☐

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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 ☐

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 MAR 2022 00:01
Patient Cloud Close Date & Time	22 MAR 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 APR 2022 00:01
Patient Cloud Close Date & Time	05 APR 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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°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 ☐

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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 ☐

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

Patient Cloud Open Date & Time	22 APR 2022 00:01
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Patient Cloud Close Date & Time	26 APR 2022 23:59
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US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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 ☐

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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 ☐

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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 ☐

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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 ☐

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

15 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

DAY 642

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

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

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

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

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

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

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

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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 ☐

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 2022 00:01
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Patient Cloud Close Date & Time	23 AUG 2022 23:59
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US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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 ☐

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

Patient Cloud Open Date & Time	26 AUG 2022 00:01
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Patient Cloud Close Date & Time	30 AUG 2022 23:59
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US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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="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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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="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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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°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 ☐

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 2022 00:01
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Patient Cloud Close Date & Time	27 SEP 2022 23:59
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US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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 <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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 2022 00:01
Patient Cloud Close Date & Time	18 OCT 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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 <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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Close Date & Time](#)

15 NOV 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

[Patient Cloud Close Date & Time](#)

22 NOV 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 2022 00:01
Patient Cloud Close Date & Time	29 NOV 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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 ☐

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 DEC 2022 00:01
Patient Cloud Close Date & Time	06 DEC 2022 23:59

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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 ☐

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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 ☐

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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"/>

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

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

Patient Cloud Open Date & Time	23 DEC 2022 00:01
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Patient Cloud Close Date & Time	27 DEC 2022 23:59
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US3642333

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:18:10

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

US3642333

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

Was Contact Attempted? Yes ☐
No ☒

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

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

Comments

If Contact Not Made, please provide Comments _____

US3642333

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642333

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:15:49

Generated On: 10 Jun 2021 09:18:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 FEB 2021

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

ATTEMPT MADE ON 18FEB2021
LEFT VOICE MESSAGE TO CALL

If Contact Not Made, please provide Comments

(b) (6)

US3642333

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:15:49

Generated On: 10 Jun 2021 09:18:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642333

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 20 Mar 2021 00:04:40

Generated On: 10 Jun 2021 09:18:10

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

US3642333

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 20 Mar 2021 00:04:40

Generated On: 10 Jun 2021 09:18:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642333

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Apr 2021 18:08:37

Generated On: 10 Jun 2021 09:18:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642333

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Apr 2021 18:08:37

Generated On: 10 Jun 2021 09:18:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642333

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:18:10

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 _____

US3642333

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:10

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)	

US3642333

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:18:10

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.

US3642333

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:18:10

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/>

US3642333

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:10

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3642333

Folder: Covid-19 Assessment (2)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:18:10

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"/>

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

Date of Contact	19 DEC 2020
Time of Contact	08:00
Date and Time of Contact (derived)	19 DEC 2020 08:00
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 03 Apr 2021 23:36:32

Generated On: 10 Jun 2021 09:18:10

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 03 Apr 2021 23:36:32

Generated On: 10 Jun 2021 09:18:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 DEC 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 03 Apr 2021 23:36:32

Generated On: 10 Jun 2021 09:18:10

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 03 Apr 2021 23:36:32

Generated On: 10 Jun 2021 09:18:10

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

Date of Visit 19 DEC 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒ No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☒ No ☐

Date of Test 19 DEC 2020

Type of Test Performed Nasopharyngeal Swab ☒
Nasal Swab ☐
Saliva Test ☐
Other ☐

Other, specify

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☒ No ☐

If yes, provide lab information below

Lab/ Institution Test Performed SUBJECT REPORTS COVID19
NASOPHARYNGEAL SWAB
TEST PERFORMED AT
ENSENADA, MEXICO
HOSPITAL.

CLIA Certified? Yes ☐ No ☒

COVID-19 Positive (CSA Programming Field Only) 1

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date _____

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Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

If Yes to either Did subject require any of the following:

Ventilator Support:

High-Flow Oxygen?

Yes ☐

No ☒

Start Date

End Date

Non-Invasive Ventilation?

Yes ☐

No ☒

Start Date

End Date

Mechanical Ventilation?

Yes ☐

No ☒

Start Date

End Date

ECMO?

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors

Yes ☐

No ☒

Start Date

End Date

Acute Renal Dysfunction?

Yes ☐

No ☒

Start Date

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Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☐

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☒
No ☐

Start Date 19 DEC 2020

End Date 01 JAN 2021

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

US3642333

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

Form: Visit Date

Generated On: 10 Jun 2021 09:18:10

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 _____

US3642333

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

Form: Unblinding

Generated On: 10 Jun 2021 09:18:10

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

US3642333

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:18:10

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/>

US3642333

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:18:10

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/>

US3642333

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Feb 2021 19:37:58

Generated On: 10 Jun 2021 09:18:10

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3642333

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 00:03:17

Generated On: 10 Jun 2021 09:18:10

AEID	USA-US109-2021-MRNA-1273-P30 1000001
Adverse event	COVID19
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 checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	19 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	04 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	19 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	01 JAN 2021
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 00:03:17

Generated On: 10 Jun 2021 09:18:10

Number of Days in ICU	14
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative	

US3642333

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 00:03:17

Generated On: 10 Jun 2021 09:18:10

SUBJECT REPORTS THAT HE
WAS HOSPITALIZED IN THE ICU
AT ENSENADA, MEXICO FOR
COVID19. HE BEGAN TO FEEL
COVID19 SYMPTOMS ON
19DEC2020 BUT DID NOT CALL
US SINCE HE WAS OUT OF
COUNTRY. HE LATER WAS
HOSPITALIZED IN CRITICAL
CONDITION AND HAS
RECOVERED SINCE THEN.

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)	1

US3642333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

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

Yes ☒

No ☐

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

US3642333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 13 Feb 2021 19:37:58

Generated On: 10 Jun 2021 09:18:10

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE II

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3642333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 13 Feb 2021 19:37:58

Generated On: 10 Jun 2021 09:18:10

	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 MAY 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3642333

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 13 Feb 2021 19:37:59

Generated On: 10 Jun 2021 09:18:10

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3642333

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:18:10

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

US3642333

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:18:10

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 ☐

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 09 Apr 2021 00:03:17

Generated On: 10 Jun 2021 09:18:10

SAEID	USA-US109-2021-MRNA-1273-P301000001
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	STEPHEN
Investigator's Last Name	SPECTOR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 09 Apr 2021 00:03:17

Generated On: 10 Jun 2021 09:18:10

SAEID	USA-US109-2021-MRNA-1273-P301000001
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	STEPHEN
Investigator's Last Name	SPECTOR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	04/JAN/2021 10:53
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

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 09 Apr 2021 00:03:17

Generated On: 10 Jun 2021 09:18:10

SAEID	USA-US109-2021-MRNA-1273-P301000001
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	STEPHEN
Investigator's Last Name	SPECTOR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	03/FEB/2021 13:12
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 09 Apr 2021 00:03:17

Generated On: 10 Jun 2021 09:18:10

SAEID	USA-US109-2021-MRNA-1273-P301000001
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	STEPHEN
Investigator's Last Name	SPECTOR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	07/APR/2021 12:22
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

US3642333 (Prod: University of California San Diego)

US3642333

Form: Participant Creation

Generated On: 10 Jun 2021 09:18:10

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'US3642333'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Oct 2020 20:53:31

US3642333

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:18:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4)	21 Oct 2020 20:58:22

US3642333

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '21 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Oct 2020 20:53:32

US3642333

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:18:10

[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 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Clinic (Clinic)'	Megan Loughran (b) (4)	21 Oct 2020 20:58:22

US3642333

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:18:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User entered 'SCRN'	System	21 Oct 2020 20:58:22

US3642333

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:18:10

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User closed query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity sample collected for Visit 1 Day 1, the Birth Year is missing, however, the CRF has Year of Birth recorded as 1947. Please clarify the subject's Year of Birth and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 06:45:16
Query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity sample collected for Visit 1 Day 1, the Birth Year is missing, however, the CRF has Year of Birth recorded as 1947. Please clarify the subject's Year of Birth and update as appropriate.' answered with 'MRN (b) (6)' (Site from DM).	Megan Loughran (b) (4) (b) (4)	10 Nov 2020 23:53:19
User opened query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity sample collected for Visit 1 Day 1, the Birth Year is missing, however, the CRF has Year of Birth recorded as 1947. Please clarify the subject's Year of Birth and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 21:59:29
User entered (b) (6) 1947'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Oct 2020 20:53:33

US3642333

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:18:10

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '72'	(b) (4) Megan Loughran (b) (4)	21 Oct 2020 20:58:41

US3642333

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:18:10

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User entered 'YEARS'	System	21 Oct 2020 20:58:41

US3642333

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:18:10

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User entered '73'	System	21 Oct 2020 20:58:57

US3642333

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:18:10

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User closed query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity sample collected for Visit 1 Day 1 has no data recorded for the subject's sex, however, the CRF has Sex recorded as Male. Please clarify the subject's Sex and update if appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 13:30:54
Query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity sample collected for Visit 1 Day 1 has no data recorded for the subject's sex, however, the CRF has Sex recorded as Male. Please clarify the subject's Sex and update if appropriate.' answered with 'data are correct as entered in edc' (Site from DM).	Megan Loughran (b) (4) (b) (4)	10 Nov 2020 23:53:31
User opened query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity sample collected for Visit 1 Day 1 has no data recorded for the subject's sex, however, the CRF has Sex recorded as Male. Please clarify the subject's Sex and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	31 Oct 2020 14:34:09
User entered 'Male (M)'	Megan Loughran (b) (4) (b) (4)	21 Oct 2020 20:58:41

US3642333

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:18:10

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4) Megan Loughran (b) (4)	21 Oct 2020 20:58:41

US3642333

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:18:10

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'I'	(b) (4) Megan Loughran (b) (4)	21 Oct 2020 20:58:41

US3642333

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:18:10

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '0'	(b) (4) Megan Loughran (b) (4)	21 Oct 2020 20:58:41

US3642333

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:18:10

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '0'	(b) (4) Megan Loughran (b) (4)	21 Oct 2020 20:58:41

US3642333

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:18:10

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '0'	(b) (4) Megan Loughran (b) (4)	21 Oct 2020 20:58:41

US3642333

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:18:10

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '0'	Megan Loughran (b) (4)	21 Oct 2020 20:58:41

US3642333

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:18:10

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '0'	(b) (4) Megan Loughran (b) (4)	21 Oct 2020 20:58:41

US3642333

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:18:10

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Megan Loughran (b) (4)	21 Oct 2020 20:58:41

US3642333

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:18:10

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '0'	(b) (4) Megan Loughran (b) (4)	21 Oct 2020 20:58:41

US3642333

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:18:10

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '0'	(b) (4) Megan Loughran (b) (4)	21 Oct 2020 20:58:41

US3642333

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:18:10

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '21 Oct 2020'	(b) (4) Megan Loughran (b) (4)	21 Oct 2020 20:58:57

US3642333

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User entered 'Oct 2020'	System	21 Oct 2020 20:58:57

US3642333

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User entered '2020'	System	21 Oct 2020 20:58:57

US3642333

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:18:10

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Amendment 4 (4)'	(b) (4) Megan Loughran (b) (4)	21 Oct 2020 20:58:57

US3642333

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4)	21 Oct 2020 20:58:57

US3642333

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Megan Loughran (b) (4)	21 Oct 2020 20:58:57

US3642333

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:18:10

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Megan Loughran (b) (4)	21 Oct 2020 20:58:57

US3642333

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:18:10

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4)	21 Oct 2020 20:58:57

US3642333

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:18:10

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Oct 2020 20:53:32

US3642333

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:18:10

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User entered 'I'	System	21 Oct 2020 20:59:02

US3642333

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	Megan Loughran (b) (4)	21 Oct 2020 20:59:02

US3642333

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:18:10

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	Son Do (b) (4)	23 Oct 2020 14:56:43

US3642333

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:18:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	23 Oct 2020 14:58:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 14:58:29
Data point term sent to Coder	System	23 Oct 2020 14:57:37
User entered 'type 2 diabetes'	Son Do (b) (4)	23 Oct 2020 14:57:22

US3642333

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'UN May 2000'	Son Do (b) (4)	23 Oct 2020 14:57:22

US3642333

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:18:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '0'	Son Do (b) (4)	23 Oct 2020 14:57:22

US3642333

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:18:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 14:57:30
User entered 'Yes (Y)' reason for change: Data Entry Error	System	23 Oct 2020 14:57:30
User opened query 'Data is required. Please complete.' (Site from System).	Son Do (b) (4)	23 Oct 2020 14:57:22
User entered empty.	System	23 Oct 2020 14:57:22

US3642333

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	Son Do (b) (4)	23 Oct 2020 14:57:22

US3642333

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:18:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '0'	Son Do (b) (4)	23 Oct 2020 14:57:22

US3642333

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User entered 'May 2000'	System	23 Oct 2020 14:57:22

US3642333

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User entered '2000'	System	23 Oct 2020 14:57:22

US3642333

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User entered empty.	System	23 Oct 2020 14:57:22

US3642333

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User entered empty.	System	23 Oct 2020 14:57:22

US3642333

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	Son Do (b) (4)	23 Oct 2020 14:59:29

US3642333

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '21 Oct 2020'	Son Do (b) (4)	23 Oct 2020 14:59:29

US3642333

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '13:26'	Son Do (b) (4)	23 Oct 2020 14:59:29

US3642333

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User entered '21 Oct 2020 13:26'	System	23 Oct 2020 14:59:29

US3642333

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '176' cm	(b) (4)	23 Oct 2020 14:59:29
DataPoint set to visible.	Son Do (b) (4)	21 Oct 2020 20:59:02
	System	

US3642333

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '82.7' kg	(b) (4)	23 Oct 2020 14:59:29
DataPoint set to visible.	Son Do (b) (4)	21 Oct 2020 20:59:02
	System	

US3642333

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User entered '26.69809'	System	23 Oct 2020 14:59:29
DataPoint set to visible.	System	21 Oct 2020 20:59:02

US3642333

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:10

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User entered 'kg/m2'	System	23 Oct 2020 14:59:29
DataPoint set to visible.	System	21 Oct 2020 20:59:02

US3642333

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered missing code ND - Not Done.	Son Do (b) (4)	23 Oct 2020 14:59:29

US3642333

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	Son Do (b) (4)	23 Oct 2020 14:59:29

US3642333

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	Son Do (b) (4)	23 Oct 2020 14:59:29

US3642333

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered missing code ND - Not Done.	Son Do (b) (4)	23 Oct 2020 14:59:29

US3642333

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User entered 'bpm'	System	23 Oct 2020 14:59:29

US3642333

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered missing code ND - Not Done.	Son Do (b) (4)	23 Oct 2020 14:59:29

US3642333

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User entered 'breaths/min'	System	23 Oct 2020 14:59:29

US3642333

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered missing code ND - Not Done.	Son Do (b) (4)	23 Oct 2020 14:59:29

US3642333

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User entered 'mmHg'	System	23 Oct 2020 14:59:29

US3642333

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered missing code ND - Not Done.	Son Do (b) (4)	23 Oct 2020 14:59:29

US3642333

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User entered 'mmHg'	System	23 Oct 2020 14:59:29

US3642333

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:10

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53

US3642333

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:10

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53

US3642333

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:18:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	Son Do (b) (4)	23 Oct 2020 14:58:55

US3642333

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:18:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '21 Oct 2020'	Son Do (b) (4)	23 Oct 2020 14:58:55

US3642333

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:10

[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 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)'	Son Do (b) (4)	23 Oct 2020 15:01:10

US3642333

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:10

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 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)'	Son Do (b) (4)	23 Oct 2020 15:01:10

US3642333

Folder: Screening

Form: Risk of Exposure

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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 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)'	Son Do (b) (4)	23 Oct 2020 15:01:10

US3642333

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:10

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 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)'	Son Do (b) (4)	23 Oct 2020 15:01:10

US3642333

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:10

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 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)'	Son Do (b) (4)	23 Oct 2020 15:01:10

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:10

[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 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)'	Son Do (b) (4)	23 Oct 2020 15:01:10

US3642333

Folder: Screening

Form: Risk of Exposure

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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 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)'	Son Do (b) (4)	23 Oct 2020 15:01:10

US3642333

Folder: Screening

Form: Risk of Exposure

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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 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)'	Son Do (b) (4)	23 Oct 2020 15:01:10

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Folder: Screening

Form: Risk of Exposure

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[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 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)'	Son Do (b) (4)	23 Oct 2020 15:01:10

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Folder: Screening

Form: Risk of Exposure

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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 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)'	Son Do (b) (4)	23 Oct 2020 15:01:10

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Folder: Screening

Form: Risk of Exposure

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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 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)'	Son Do (b) (4)	23 Oct 2020 15:01:10

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:10

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)'	Son Do (b) (4)	23 Oct 2020 15:01:10

US3642333

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:10

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	Son Do (b) (4)	23 Oct 2020 15:01:10

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:10

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '0'	Son Do (b) (4)	23 Oct 2020 15:01:10

US3642333

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:10

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '0'	Son Do (b) (4)	23 Oct 2020 15:01:10

US3642333

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:10

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 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '0'	Son Do (b) (4)	23 Oct 2020 15:01:10

US3642333

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:10

[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 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '0'	Son Do (b) (4)	23 Oct 2020 15:01:10

US3642333

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:10

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 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '0'	Son Do (b) (4)	23 Oct 2020 15:01:10

US3642333

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:10

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'I'	Son Do (b) (4)	23 Oct 2020 15:01:10

US3642333

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:10

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '0'	Son Do (b) (4)	23 Oct 2020 15:01:10

US3642333

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:10

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:41:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	Son Do (b) (4)	23 Oct 2020 15:01:10

US3642333

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:18:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4)	21 Oct 2020 20:59:13

US3642333

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '21 Oct 2020'	(b) (4) Megan Loughran (b) (4)	21 Oct 2020 20:59:13

US3642333

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Clinic (Clinic)'	Megan Loughran (b) (4)	21 Oct 2020 20:59:13

US3642333

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:18:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User entered 'VISIT1'	System	21 Oct 2020 20:59:13

US3642333

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '21 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Oct 2020 20:53:39

US3642333

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:18:10

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '191544'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Oct 2020 20:53:39

US3642333

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:18:10

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Oct 2020 20:53:39

US3642333

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:18:10

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)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4)	21 Oct 2020 20:59:41

US3642333

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:18:10

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)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)'	Megan Loughran (b) (4)	21 Oct 2020 20:59:41

US3642333

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:18:10

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4)	21 Oct 2020 20:59:41

US3642333

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:18:10

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4)	21 Oct 2020 20:59:41

US3642333

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:18:10

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4)	21 Oct 2020 20:59:41

US3642333

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:18:10

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4)	21 Oct 2020 20:59:41
DataPoint set to visible.	(b) (4) System	21 Oct 2020 20:58:57

US3642333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:18:10

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered missing code ND - Not Done.	Son Do (b) (4)	23 Oct 2020 15:00:14

US3642333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:18:10

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered missing code ND - Not Done.	Son Do (b) (4)	23 Oct 2020 15:00:14

US3642333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:18:10

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered missing code ND - Not Done.	Son Do (b) (4)	23 Oct 2020 15:00:14

US3642333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:18:10

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered missing code ND - Not Done.	Son Do (b) (4)	23 Oct 2020 15:00:14

US3642333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User accepted default value 'Pre-Dose (PREDOSE)'	Son Do (b) (4)	23 Oct 2020 15:00:14

US3642333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	Son Do (b) (4)	23 Oct 2020 15:00:14

US3642333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '21 Oct 2020'	Son Do (b) (4)	23 Oct 2020 15:00:14

US3642333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '13:26'	Son Do (b) (4)	23 Oct 2020 15:00:14

US3642333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User entered '21 Oct 2020 13:26'	System	23 Oct 2020 15:00:14

US3642333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '98.2' F	Son Do (b) (4)	23 Oct 2020 15:00:14

US3642333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Oral (Oral)'	Son Do (b) (4)	23 Oct 2020 15:00:14

US3642333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	Son Do (b) (4)	23 Oct 2020 15:00:14

US3642333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '73'	Son Do (b) (4)	23 Oct 2020 15:00:14

US3642333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User entered 'bpm'	System	23 Oct 2020 15:00:14

US3642333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '20'	Son Do (b) (4)	23 Oct 2020 15:00:14

US3642333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User entered 'breaths/min'	System	23 Oct 2020 15:00:14

US3642333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '118'	Son Do (b) (4)	23 Oct 2020 15:00:14

US3642333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User entered 'mmHg'	System	23 Oct 2020 15:00:14

US3642333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '74'	Son Do (b) (4)	23 Oct 2020 15:00:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User entered 'mmHg'	System	23 Oct 2020 15:00:14

US3642333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:18:10

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered missing code ND - Not Done.	Son Do (b) (4)	23 Oct 2020 15:00:14

US3642333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:18:10

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered missing code ND - Not Done.	Son Do (b) (4)	23 Oct 2020 15:00:14

US3642333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User accepted default value 'Post-Dose (POSTDOSE)'	Son Do (b) (4)	23 Oct 2020 15:00:14

US3642333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	Son Do (b) (4)	23 Oct 2020 15:00:14

US3642333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '21 Oct 2020'	Son Do (b) (4)	23 Oct 2020 15:00:14

US3642333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '15:35'	Son Do (b) (4)	23 Oct 2020 15:00:14

US3642333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User entered '21 Oct 2020 15:35'	System	23 Oct 2020 15:00:14

US3642333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '97.3' F	Son Do (b) (4)	23 Oct 2020 15:00:14

US3642333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Oral (Oral)'	Son Do (b) (4)	23 Oct 2020 15:00:14

US3642333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	Son Do (b) (4)	23 Oct 2020 15:00:14

US3642333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '75'	Son Do (b) (4)	23 Oct 2020 15:00:14

US3642333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User entered 'bpm'	System	23 Oct 2020 15:00:14

US3642333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '20'	Son Do (b) (4)	23 Oct 2020 15:00:14

US3642333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User entered 'breaths/min'	System	23 Oct 2020 15:00:14

US3642333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '124'	Son Do (b) (4)	23 Oct 2020 15:00:14

US3642333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User entered 'mmHg'	System	23 Oct 2020 15:00:14

US3642333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '71'	Son Do (b) (4)	23 Oct 2020 15:00:14

US3642333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User entered 'mmHg'	System	23 Oct 2020 15:00:14

US3642333

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:18:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Son Do	04 Feb 2021 18:17:46
User entered 'Yes (Y)'	Son Do (b) (4)	23 Oct 2020 14:59:04

US3642333

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:18:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty; reason for change Data Entry Error	(b) (4)	
	Son Do (b) (4)	04 Feb 2021 18:17:46
User entered '21 Oct 2020'	Son Do (b) (4)	23 Oct 2020 14:59:04

US3642333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:18:10

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4)	21 Oct 2020 22:13:23

US3642333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:18:10

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Megan Loughran (b) (4)	21 Oct 2020 22:13:23

US3642333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Megan Loughran (b) (4)	21 Oct 2020 22:13:23

US3642333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:18:10

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User entered 'MRNA-1273 OR PLACEBO'	System	21 Oct 2020 22:13:23

US3642333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:18:10

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '21 Oct 2020'	(b) (4) Megan Loughran (b) (4)	21 Oct 2020 22:13:23

US3642333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:18:10

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '14:54'	(b) (4) Megan Loughran (b) (4)	21 Oct 2020 22:13:23

US3642333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:18:10

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User entered '21 Oct 2020 14:54'	System	21 Oct 2020 22:13:23

US3642333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:18:10

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Left Arm (LEFT ARM)'	Megan Loughran (b) (4)	21 Oct 2020 22:13:23

US3642333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:18:10

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User entered 'ONCE'	System	21 Oct 2020 22:13:23

US3642333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:18:10

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User entered 'INTRAMUSCULAR'	System	21 Oct 2020 22:13:23

US3642333

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:18:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	Son Do (b) (4)	23 Oct 2020 15:00:26

US3642333

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:18:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '21 Oct 2020'	Son Do (b) (4)	23 Oct 2020 15:00:26

US3642333

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:18:10

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '14:02'	Son Do (b) (4)	23 Oct 2020 15:00:26

US3642333

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:18:10

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User entered '21 Oct 2020 14:02'	System	23 Oct 2020 15:00:26

US3642333

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:18:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '21 Oct 2020'	Son Do (b) (4)	23 Oct 2020 15:00:38

US3642333

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:18:10

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Son Do (b) (4)	23 Oct 2020 15:00:38

US3642333

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:18:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	Son Do (b) (4)	23 Oct 2020 15:00:38

US3642333

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:18:10

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '14:07'	Son Do (b) (4)	23 Oct 2020 15:00:38

US3642333

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:18:10

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User entered '21 Oct 2020 14:07'	System	23 Oct 2020 15:00:38

US3642333

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:18:10

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User accepted default value 'Nasopharyngeal Swab 2 Son Do (NASAL2)'	(b) (4)	23 Oct 2020 15:00:38

US3642333

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:18:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)'	Son Do (b) (4)	23 Oct 2020 15:00:38

US3642333

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:18:10

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	Son Do (b) (4)	23 Oct 2020 15:00:38

US3642333

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:18:10

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User entered empty.	System	23 Oct 2020 15:00:38

US3642333

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:18:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	Son Do (b) (4)	23 Oct 2020 15:00:43

US3642333

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:18:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User entered 'I'	System	23 Oct 2020 15:00:43

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	21 Oct 2020 22:13:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-21T15:24:31', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'a33de643-7675-4ed5-b830-be2bdad5139b' User entered 'Yes (Y)'	System	21 Oct 2020 22:25:05
	System	21 Oct 2020 22:25:05

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-21T15:24:47', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'a33de643-7675-4ed5-b830-be2bdad5139b' User entered '97.3'	System	21 Oct 2020 22:25:05
	System	21 Oct 2020 22:25:05

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-21T15:24:54', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'a33de643-7675-4ed5-b830-be2bdad5139b' User entered 'No (N)'	System	21 Oct 2020 22:25:05
	System	21 Oct 2020 22:25:05

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-21T15:25:01', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'a33de643-7675-4ed5-b830-be2bdad5139b' User entered '21 Oct 2020 15:25'	System	21 Oct 2020 22:25:05
	System	21 Oct 2020 22:25:05

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '21 Oct 2020 15:14'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '21 Oct 2020 17:44'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	21 Oct 2020 22:13:23
User entered 'Day 1, after vaccination (at home)'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-21T20:02:20', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '84f13d11-ce1d-47bb-b7fd-7adb62d4d9be' User entered 'Yes (Y)'	System	22 Oct 2020 03:02:52
	System	22 Oct 2020 03:02:52

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-21T20:02:30', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '84f13d11-ce1d-47bb-b7fd-7adb62d4d9be' User entered '97.3'	System	22 Oct 2020 03:02:52
	System	22 Oct 2020 03:02:52

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-21T20:02:37', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '84f13d11-ce1d-47bb-b7fd-7adb62d4d9be' User entered 'No (N)'	System	22 Oct 2020 03:02:52
	System	22 Oct 2020 03:02:52

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-21T20:02:50', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '84f13d11-ce1d-47bb-b7fd-7adb62d4d9be' User entered '21 Oct 2020 20:02'	System	22 Oct 2020 03:02:52
	System	22 Oct 2020 03:02:52

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '21 Oct 2020 18:39'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '22 Oct 2020 11:59'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	21 Oct 2020 22:13:23
User entered 'Day 2'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:18:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-22T20:02:06', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'd398ab18-8a2b-4408-bcd3-6fdc457cc450' User entered 'Yes (Y)'	System	23 Oct 2020 03:02:30
	System	23 Oct 2020 03:02:30

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:18:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-22T20:02:16', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'd398ab18-8a2b-4408-bcd3-6fdc457cc450' User entered '96.4'	System	23 Oct 2020 03:02:30
	System	23 Oct 2020 03:02:30

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-22T20:02:21', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'd398ab18-8a2b-4408-bcd3-6fdc457cc450'	System	23 Oct 2020 03:02:30
User entered 'No (N)'	System	23 Oct 2020 03:02:30

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:18:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-22T20:02:25', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'd398ab18-8a2b-4408-bcd3-6fdc457cc450' User entered '22 Oct 2020 20:02'	System	23 Oct 2020 03:02:30
	System	23 Oct 2020 03:02:30

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	21 Oct 2020 22:13:23
User entered 'Day 3'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:18:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-23T20:12:56', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'f9ff21fa-3de5-4cd0-8469-0b9efa869457' User entered 'Yes (Y)'	System	24 Oct 2020 03:13:17
	System	24 Oct 2020 03:13:17

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:18:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-23T20:13:07', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'f9ff21fa-3de5-4cd0-8469-0b9efa869457' User entered '97.1'	System	24 Oct 2020 03:13:17
	System	24 Oct 2020 03:13:17

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-23T20:13:11', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'f9ff21fa-3de5-4cd0-8469-0b9efa869457'	System	24 Oct 2020 03:13:17
User entered 'No (N)'	System	24 Oct 2020 03:13:17

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:18:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-23T20:13:15', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'f9ff21fa-3de5-4cd0-8469-0b9efa869457' User entered '23 Oct 2020 20:13'	System	24 Oct 2020 03:13:17
	System	24 Oct 2020 03:13:17

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	21 Oct 2020 22:13:23
User entered 'Day 4'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:18:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-24T20:06:18', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '3aefa347-25a7-4470-addb-5f0359b1d501' User entered 'Yes (Y)'	System	25 Oct 2020 03:06:40
	System	25 Oct 2020 03:06:40

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:18:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-24T20:06:27', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '3aefa347-25a7-4470-addb-5f0359b1d501' User entered '96.6'	System	25 Oct 2020 03:06:40
	System	25 Oct 2020 03:06:40

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-24T20:06:33', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '3aefa347-25a7-4470-addb-5f0359b1d501' User entered 'No (N)'	System	25 Oct 2020 03:06:40
	System	25 Oct 2020 03:06:40

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:18:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-24T20:06:38', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '3aefa347-25a7-4470-addb-5f0359b1d501' User entered '24 Oct 2020 20:06'	System	25 Oct 2020 03:06:40
	System	25 Oct 2020 03:06:40

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '24 Oct 2020 12:00'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '25 Oct 2020 11:59'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	21 Oct 2020 22:13:23
User entered 'Day 5'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:18:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-25T20:00:48', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '855e9921-2638-4092-8975-232623ddf245' User entered 'Yes (Y)'	System	26 Oct 2020 03:01:11
	System	26 Oct 2020 03:01:11

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:18:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-25T20:00:56', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '855e9921-2638-4092-8975-232623ddf245' User entered '96.6'	System	26 Oct 2020 03:01:11
	System	26 Oct 2020 03:01:11

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-25T20:01:00', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '855e9921-2638-4092-8975-232623ddf245'	System	26 Oct 2020 03:01:11
User entered 'No (N)'	System	26 Oct 2020 03:01:11

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:18:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-25T20:01:08', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '855e9921-2638-4092-8975-232623ddf245' User entered '25 Oct 2020 20:01'	System	26 Oct 2020 03:01:11
	System	26 Oct 2020 03:01:11

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '25 Oct 2020 12:00'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '26 Oct 2020 11:59'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	21 Oct 2020 22:13:23
User entered 'Day 6'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:18:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-26T20:09:44', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '2f8c7f39-a538-4f29-91dd-a08d694e0805'	System	27 Oct 2020 03:10:03
User entered 'Yes (Y)'	System	27 Oct 2020 03:10:03

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:18:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-26T20:09:52', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '2f8c7f39-a538-4f29-91dd-a08d694e0805' User entered '97.8'	System	27 Oct 2020 03:10:03
	System	27 Oct 2020 03:10:03

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-26T20:09:57', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '2f8c7f39-a538-4f29-91dd-a08d694e0805'	System	27 Oct 2020 03:10:03
User entered 'No (N)'	System	27 Oct 2020 03:10:03

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:18:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-26T20:10:01', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '2f8c7f39-a538-4f29-91dd-a08d694e0805' User entered '26 Oct 2020 20:10'	System	27 Oct 2020 03:10:03
	System	27 Oct 2020 03:10:03

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '26 Oct 2020 12:00'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '27 Oct 2020 11:59'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	21 Oct 2020 22:13:23
User entered 'Day 7'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:18:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-27T20:09:10', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '477d84de-8ef7-4ec1-85ae-f26baac63ba5' User entered 'Yes (Y)'	System	28 Oct 2020 03:09:28
	System	28 Oct 2020 03:09:28

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:18:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-27T20:09:17', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '477d84de-8ef7-4ec1-85ae-f26baac63ba5' User entered '97.5'	System	28 Oct 2020 03:09:28
	System	28 Oct 2020 03:09:28

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-27T20:09:22', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '477d84de-8ef7-4ec1-85ae-f26baac63ba5' User entered 'No (N)'	System	28 Oct 2020 03:09:28
	System	28 Oct 2020 03:09:28

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:18:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-27T20:09:25', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '477d84de-8ef7-4ec1-85ae-f26baac63ba5' User entered '27 Oct 2020 20:09'	System	28 Oct 2020 03:09:28
	System	28 Oct 2020 03:09:28

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '27 Oct 2020 12:00'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '28 Oct 2020 11:59'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	21 Oct 2020 22:13:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-21T15:25:22', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '45eb3e6f-4b72-4583-bebc-b51c408eedfd' User entered 'None (1)'	System	21 Oct 2020 22:26:27
	System	21 Oct 2020 22:26:27

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-21T15:25:43', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '45eb3e6f-4b72-4583-bebc-b51c408eedfd' User entered 'No (N)'	System	21 Oct 2020 22:26:27
	System	21 Oct 2020 22:26:27

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-21T15:25:54', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '45eb3e6f-4b72-4583-bebc-b51c408eedfd' User entered 'No (N)'	System	21 Oct 2020 22:26:27
	System	21 Oct 2020 22:26:27

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-21T15:26:06', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '45eb3e6f-4b72-4583-bebc-b51c408eedfd' User entered 'None (1)'	System	21 Oct 2020 22:26:27
	System	21 Oct 2020 22:26:27

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-21T15:26:21', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '45eb3e6f-4b72-4583-bebc-b51c408eedfd' User entered '21 Oct 2020 15:26'	System	21 Oct 2020 22:26:27
	System	21 Oct 2020 22:26:27

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '21 Oct 2020 15:14'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '21 Oct 2020 17:44'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	21 Oct 2020 22:13:23
User entered 'Day 1, after vaccination (at home)'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-21T20:04:55', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '5c6cdf37-0758-44d8-9a66-801bda609672' User entered 'None (1)'	System	22 Oct 2020 03:05:19
	System	22 Oct 2020 03:05:19

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-21T20:04:59', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '5c6cdf37-0758-44d8-9a66-801bda609672' User entered 'No (N)'	System	22 Oct 2020 03:05:19
	System	22 Oct 2020 03:05:19

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-21T20:05:04', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '5c6cdf37-0758-44d8-9a66-801bda609672' User entered 'No (N)'	System	22 Oct 2020 03:05:19
	System	22 Oct 2020 03:05:19

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-21T20:05:10', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '5c6cdf37-0758-44d8-9a66-801bda609672'	System	22 Oct 2020 03:05:19
User entered 'None (1)'	System	22 Oct 2020 03:05:19

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-21T20:05:17', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '5c6cdf37-0758-44d8-9a66-801bda609672' User entered '21 Oct 2020 20:05'	System	22 Oct 2020 03:05:19
	System	22 Oct 2020 03:05:19

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '21 Oct 2020 18:39'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '22 Oct 2020 11:59'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	21 Oct 2020 22:13:23
User entered 'Day 2'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:18:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-22T20:02:32', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '49ffeedc-2ae2-4507-96f6-f3f5fc86f72c' User entered 'None (1)'	System	23 Oct 2020 03:02:52
	System	23 Oct 2020 03:02:52

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:18:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-22T20:02:36', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '49ffeedc-2ae2-4507-96f6-f3f5fc86f72c' User entered 'No (N)'	System	23 Oct 2020 03:02:52
	System	23 Oct 2020 03:02:52

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-22T20:02:40', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '49ffeedc-2ae2-4507-96f6-f3f5fc86f72c' User entered 'No (N)'	System	23 Oct 2020 03:02:52
	System	23 Oct 2020 03:02:52

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:18:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-22T20:02:45', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '49ffeedc-2ae2-4507-96f6-f3f5fc86f72c' User entered 'None (1)'	System	23 Oct 2020 03:02:52
	System	23 Oct 2020 03:02:52

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:18:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-22T20:02:50', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '49ffeedc-2ae2-4507-96f6-f3f5fc86f72c' User entered '22 Oct 2020 20:02'	System	23 Oct 2020 03:02:52
	System	23 Oct 2020 03:02:52

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	21 Oct 2020 22:13:23
User entered 'Day 3'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:18:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-23T20:13:22', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '6d2458b9-9d17-4aae-b3a2-ab577a9d2878' User entered 'None (1)'	System	24 Oct 2020 03:13:45
	System	24 Oct 2020 03:13:45

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:18:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-23T20:13:26', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '6d2458b9-9d17-4aae-b3a2-ab577a9d2878' User entered 'No (N)'	System	24 Oct 2020 03:13:45
	System	24 Oct 2020 03:13:45

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-23T20:13:32', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '6d2458b9-9d17-4aae-b3a2-ab577a9d2878' User entered 'No (N)'	System	24 Oct 2020 03:13:45
	System	24 Oct 2020 03:13:45

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:18:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-23T20:13:37', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '6d2458b9-9d17-4aae-b3a2-ab577a9d2878' User entered 'None (1)'	System	24 Oct 2020 03:13:45
	System	24 Oct 2020 03:13:45

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:18:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-23T20:13:41', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '6d2458b9-9d17-4aae-b3a2-ab577a9d2878' User entered '23 Oct 2020 20:13'	System	24 Oct 2020 03:13:45
	System	24 Oct 2020 03:13:45

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	21 Oct 2020 22:13:23
User entered 'Day 4'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:18:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-24T20:06:46', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'f37c250a-bad1-4959-9345-0970e25d77e4' User entered 'None (1)'	System	25 Oct 2020 03:07:07
	System	25 Oct 2020 03:07:07

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:18:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-24T20:06:50', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'f37c250a-bad1-4959-9345-0970e25d77e4' User entered 'No (N)'	System	25 Oct 2020 03:07:07
	System	25 Oct 2020 03:07:07

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-24T20:06:54', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'f37c250a-bad1-4959-9345-0970e25d77e4' User entered 'No (N)'	System	25 Oct 2020 03:07:07
	System	25 Oct 2020 03:07:07

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:18:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-24T20:07:00', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'f37c250a-bad1-4959-9345-0970e25d77e4' User entered 'None (1)'	System	25 Oct 2020 03:07:07
	System	25 Oct 2020 03:07:07

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:18:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-24T20:07:05', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'f37c250a-bad1-4959-9345-0970e25d77e4' User entered '24 Oct 2020 20:07'	System	25 Oct 2020 03:07:07
	System	25 Oct 2020 03:07:07

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '24 Oct 2020 12:00'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '25 Oct 2020 11:59'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	21 Oct 2020 22:13:23
User entered 'Day 5'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:18:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-25T20:01:24', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '5c06acf0-b01d-407a-91b2-7bf3796bed9e' User entered 'None (1)'	System	26 Oct 2020 03:01:47
	System	26 Oct 2020 03:01:47

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:18:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-25T20:01:28', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '5c06acf0-b01d-407a-91b2-7bf3796bed9e' User entered 'No (N)'	System	26 Oct 2020 03:01:47
	System	26 Oct 2020 03:01:47

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-25T20:01:31', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '5c06acf0-b01d-407a-91b2-7bf3796bed9e' User entered 'No (N)'	System	26 Oct 2020 03:01:47
	System	26 Oct 2020 03:01:47

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:18:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-25T20:01:38', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '5c06acf0-b01d-407a-91b2-7bf3796bed9e' User entered 'None (1)'	System	26 Oct 2020 03:01:47
	System	26 Oct 2020 03:01:47

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:18:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-25T20:01:44', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '5c06acf0-b01d-407a-91b2-7bf3796bed9e' User entered '25 Oct 2020 20:01'	System	26 Oct 2020 03:01:47
	System	26 Oct 2020 03:01:47

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '25 Oct 2020 12:00'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '26 Oct 2020 11:59'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	21 Oct 2020 22:13:23
User entered 'Day 6'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:18:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-26T20:10:06', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'c1b9ede4-82f7-43cd-be2e-3e225cda17c0'	System	27 Oct 2020 03:10:24
User entered 'None (1)'	System	27 Oct 2020 03:10:24

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:18:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-26T20:10:11', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'c1b9ede4-82f7-43cd-be2e-3e225cda17c0' User entered 'No (N)'	System	27 Oct 2020 03:10:24
	System	27 Oct 2020 03:10:24

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-26T20:10:14', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'c1b9ede4-82f7-43cd-be2e-3e225cda17c0' User entered 'No (N)'	System	27 Oct 2020 03:10:24
	System	27 Oct 2020 03:10:24

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:18:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-26T20:10:18', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'c1b9ede4-82f7-43cd-be2e-3e225cda17c0' User entered 'None (1)'	System	27 Oct 2020 03:10:24
	System	27 Oct 2020 03:10:24

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:18:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-26T20:10:21', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'c1b9ede4-82f7-43cd-be2e-3e225cda17c0' User entered '26 Oct 2020 20:10'	System	27 Oct 2020 03:10:24
	System	27 Oct 2020 03:10:24

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '26 Oct 2020 12:00'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '27 Oct 2020 11:59'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	21 Oct 2020 22:13:23
User entered 'Day 7'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:18:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-27T20:09:30', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '73a45a1a-941b-48f8-aa9c-7e21ab39070a' User entered 'None (1)'	System	28 Oct 2020 03:09:51
	System	28 Oct 2020 03:09:51

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:18:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-27T20:09:34', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '73a45a1a-941b-48f8-aa9c-7e21ab39070a' User entered 'No (N)'	System	28 Oct 2020 03:09:51
	System	28 Oct 2020 03:09:51

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-27T20:09:38', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '73a45a1a-941b-48f8-aa9c-7e21ab39070a' User entered 'No (N)'	System	28 Oct 2020 03:09:51
	System	28 Oct 2020 03:09:51

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:18:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-27T20:09:42', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '73a45a1a-941b-48f8-aa9c-7e21ab39070a' User entered 'None (1)'	System	28 Oct 2020 03:09:51
	System	28 Oct 2020 03:09:51

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:18:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-27T20:09:46', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '73a45a1a-941b-48f8-aa9c-7e21ab39070a' User entered '27 Oct 2020 20:09'	System	28 Oct 2020 03:09:51
	System	28 Oct 2020 03:09:51

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '27 Oct 2020 12:00'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '28 Oct 2020 11:59'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	21 Oct 2020 22:13:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-21T15:26:28', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'a301dfe0-41f2-4f66-9241-7a92d238cc84' User entered 'None (0)'	System	21 Oct 2020 22:27:10
	System	21 Oct 2020 22:27:10

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-21T15:26:31', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'a301dfe0-41f2-4f66-9241-7a92d238cc84' User entered 'None (0)'	System	21 Oct 2020 22:27:10
	System	21 Oct 2020 22:27:10

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-21T15:26:36', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'a301dfe0-41f2-4f66-9241-7a92d238cc84' User entered 'None (0)'	System	21 Oct 2020 22:27:10
	System	21 Oct 2020 22:27:10

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-21T15:26:40', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'a301dfe0-41f2-4f66-9241-7a92d238cc84' User entered 'None (0)'	System	21 Oct 2020 22:27:10
	System	21 Oct 2020 22:27:10

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-21T15:26:44', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'a301dfe0-41f2-4f66-9241-7a92d238cc84' User entered 'None (0)'	System	21 Oct 2020 22:27:10
	System	21 Oct 2020 22:27:10

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-21T15:26:47', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'a301dfe0-41f2-4f66-9241-7a92d238cc84' User entered 'None (0)'	System	21 Oct 2020 22:27:10
	System	21 Oct 2020 22:27:10

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-21T15:27:00', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'a301dfe0-41f2-4f66-9241-7a92d238cc84' User entered 'No (N)'	System	21 Oct 2020 22:27:10
	System	21 Oct 2020 22:27:10

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-21T15:27:05', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'a301dfe0-41f2-4f66-9241-7a92d238cc84' User entered '21 Oct 2020 15:27'	System	21 Oct 2020 22:27:10
	System	21 Oct 2020 22:27:10

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '21 Oct 2020 15:14'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '21 Oct 2020 17:44'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	21 Oct 2020 22:13:23
User entered 'Day 1, after vaccination (at home)'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-21T20:03:11', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '7972d39f-d4d5-4032-9923-11731b51b330' User entered 'None (0)'	System	22 Oct 2020 03:04:33
	System	22 Oct 2020 03:04:33

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-21T20:03:21', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '7972d39f-d4d5-4032-9923-11731b51b330' User entered 'None (0)'	System	22 Oct 2020 03:04:33
	System	22 Oct 2020 03:04:33

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-21T20:03:31', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '7972d39f-d4d5-4032-9923-11731b51b330' User entered 'None (0)'	System	22 Oct 2020 03:04:33
	System	22 Oct 2020 03:04:33

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-21T20:03:44', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '7972d39f-d4d5-4032-9923-11731b51b330' User entered 'None (0)'	System	22 Oct 2020 03:04:33
	System	22 Oct 2020 03:04:33

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-21T20:03:53', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '7972d39f-d4d5-4032-9923-11731b51b330' User entered 'None (0)'	System	22 Oct 2020 03:04:33
	System	22 Oct 2020 03:04:33

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-21T20:04:01', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '7972d39f-d4d5-4032-9923-11731b51b330' User entered 'None (0)'	System	22 Oct 2020 03:04:33
	System	22 Oct 2020 03:04:33

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-21T20:04:15', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '7972d39f-d4d5-4032-9923-11731b51b330'	System	22 Oct 2020 03:04:33
User entered 'No (N)'	System	22 Oct 2020 03:04:33

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-21T20:04:30', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '7972d39f-d4d5-4032-9923-11731b51b330' User entered '21 Oct 2020 20:04'	System	22 Oct 2020 03:04:33
	System	22 Oct 2020 03:04:33

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '21 Oct 2020 18:39'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '22 Oct 2020 11:59'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	21 Oct 2020 22:13:23
User entered 'Day 2'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-22T20:02:58', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'b05cce20-4c99-4610-8716-7e63c0963b2b' User entered 'None (0)'	System	23 Oct 2020 03:03:37
	System	23 Oct 2020 03:03:37

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-22T20:03:02', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'b05cce20-4c99-4610-8716-7e63c0963b2b' User entered 'None (0)'	System	23 Oct 2020 03:03:37
	System	23 Oct 2020 03:03:37

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-22T20:03:06', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'b05cce20-4c99-4610-8716-7e63c0963b2b' User entered 'None (0)'	System	23 Oct 2020 03:03:37
	System	23 Oct 2020 03:03:37

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-22T20:03:10', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'b05cce20-4c99-4610-8716-7e63c0963b2b' User entered 'None (0)'	System	23 Oct 2020 03:03:37
	System	23 Oct 2020 03:03:37

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-22T20:03:14', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'b05cce20-4c99-4610-8716-7e63c0963b2b' User entered 'None (0)'	System	23 Oct 2020 03:03:37
	System	23 Oct 2020 03:03:37

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-22T20:03:20', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'b05cce20-4c99-4610-8716-7e63c0963b2b' User entered 'None (0)'	System	23 Oct 2020 03:03:37
	System	23 Oct 2020 03:03:37

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-22T20:03:29', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'b05cce20-4c99-4610-8716-7e63c0963b2b' User entered 'No (N)'	System	23 Oct 2020 03:03:37
	System	23 Oct 2020 03:03:37

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-22T20:03:33', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'b05cce20-4c99-4610-8716-7e63c0963b2b' User entered '22 Oct 2020 20:03'	System	23 Oct 2020 03:03:37
	System	23 Oct 2020 03:03:37

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	21 Oct 2020 22:13:23
User entered 'Day 3'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-23T20:13:46', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'fdbcb2ff2-bdc0-4f7e-b966-0738023ceac5' User entered 'None (0)'	System	24 Oct 2020 03:14:20
	System	24 Oct 2020 03:14:20

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-23T20:13:52', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'fdb2ff2-bdc0-4f7e-b966-0738023ceac5' User entered 'None (0)'	System	24 Oct 2020 03:14:20
	System	24 Oct 2020 03:14:20

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-23T20:13:55', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'fdb2ff2-bdc0-4f7e-b966-0738023ceac5' User entered 'None (0)'	System	24 Oct 2020 03:14:20
	System	24 Oct 2020 03:14:20

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-23T20:14:01', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'fdb2ff2-bdc0-4f7e-b966-0738023ceac5' User entered 'None (0)'	System	24 Oct 2020 03:14:20
	System	24 Oct 2020 03:14:20

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-23T20:14:04', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'fdcb2ff2-bdc0-4f7e-b966-0738023ceac5' User entered 'None (0)'	System	24 Oct 2020 03:14:20
	System	24 Oct 2020 03:14:20

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-23T20:14:07', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'fdcb2ff2-bdc0-4f7e-b966-0738023ceac5' User entered 'None (0)'	System	24 Oct 2020 03:14:20
	System	24 Oct 2020 03:14:20

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-23T20:14:12', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'fdb2ff2-bdc0-4f7e-b966-0738023ceac5' User entered 'No (N)'	System	24 Oct 2020 03:14:20
	System	24 Oct 2020 03:14:20

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-23T20:14:16', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'fdcb2ff2-bdc0-4f7e-b966-0738023ceac5' User entered '23 Oct 2020 20:14'	System	24 Oct 2020 03:14:20
	System	24 Oct 2020 03:14:20

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	21 Oct 2020 22:13:23
User entered 'Day 4'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-24T20:07:11', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '54851e07-f7fb-4524-822c-04ae01a44fb4' User entered 'None (0)'	System	25 Oct 2020 03:08:01
	System	25 Oct 2020 03:08:01

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-24T20:07:17', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '54851e07-f7fb-4524-822c-04ae01a44fb4' User entered 'None (0)'	System	25 Oct 2020 03:08:01
	System	25 Oct 2020 03:08:01

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-24T20:07:24', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '54851e07-f7fb-4524-822c-04ae01a44fb4' User entered 'None (0)'	System	25 Oct 2020 03:08:01
	System	25 Oct 2020 03:08:01

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-24T20:07:31', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '54851e07-f7fb-4524-822c-04ae01a44fb4' User entered 'None (0)'	System	25 Oct 2020 03:08:01
	System	25 Oct 2020 03:08:01

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-24T20:07:37', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '54851e07-f7fb-4524-822c-04ae01a44fb4' User entered 'None (0)'	System	25 Oct 2020 03:08:01
	System	25 Oct 2020 03:08:01

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-24T20:07:45', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '54851e07-f7fb-4524-822c-04ae01a44fb4' User entered 'None (0)'	System	25 Oct 2020 03:08:01
	System	25 Oct 2020 03:08:01

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-24T20:07:48', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '54851e07-f7fb-4524-822c-04ae01a44fb4' User entered 'No (N)'	System	25 Oct 2020 03:08:01
	System	25 Oct 2020 03:08:01

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-24T20:07:57', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '54851e07-f7fb-4524-822c-04ae01a44fb4' User entered '24 Oct 2020 20:07'	System	25 Oct 2020 03:08:01
	System	25 Oct 2020 03:08:01

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '24 Oct 2020 12:00'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '25 Oct 2020 11:59'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	21 Oct 2020 22:13:23
User entered 'Day 5'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-25T20:01:56', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '72baea38-9220-4657-9b6c-e7246ee8435f' User entered 'None (0)'	System	26 Oct 2020 03:02:41
	System	26 Oct 2020 03:02:41

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-25T20:02:07', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '72baea38-9220-4657-9b6c-e7246ee8435f' User entered 'None (0)'	System	26 Oct 2020 03:02:41
	System	26 Oct 2020 03:02:41

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-25T20:02:14', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '72baea38-9220-4657-9b6c-e7246ee8435f' User entered 'None (0)'	System	26 Oct 2020 03:02:41
	System	26 Oct 2020 03:02:41

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-25T20:02:18', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '72baea38-9220-4657-9b6c-e7246ee8435f' User entered 'None (0)'	System	26 Oct 2020 03:02:41
	System	26 Oct 2020 03:02:41

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-25T20:02:22', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '72baea38-9220-4657-9b6c-e7246ee8435f' User entered 'None (0)'	System	26 Oct 2020 03:02:41
	System	26 Oct 2020 03:02:41

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-25T20:02:26', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '72baea38-9220-4657-9b6c-e7246ee8435f' User entered 'None (0)'	System	26 Oct 2020 03:02:41
	System	26 Oct 2020 03:02:41

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-25T20:02:30', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '72baea38-9220-4657-9b6c-e7246ee8435f' User entered 'No (N)'	System	26 Oct 2020 03:02:41
	System	26 Oct 2020 03:02:41

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-25T20:02:38', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '72baea38-9220-4657-9b6c-e7246ee8435f' User entered '25 Oct 2020 20:02'	System	26 Oct 2020 03:02:41
	System	26 Oct 2020 03:02:41

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '25 Oct 2020 12:00'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '26 Oct 2020 11:59'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	21 Oct 2020 22:13:23
User entered 'Day 6'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-26T20:10:27', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '7ad56b0e-a38d-4f42-a12f-063b10097617' User entered 'None (0)'	System	27 Oct 2020 03:10:56
	System	27 Oct 2020 03:10:56

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-26T20:10:32', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '7ad56b0e-a38d-4f42-a12f-063b10097617' User entered 'None (0)'	System	27 Oct 2020 03:10:56
	System	27 Oct 2020 03:10:56

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-26T20:10:34', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '7ad56b0e-a38d-4f42-a12f-063b10097617' User entered 'None (0)'	System	27 Oct 2020 03:10:56
	System	27 Oct 2020 03:10:56

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-26T20:10:38', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '7ad56b0e-a38d-4f42-a12f-063b10097617' User entered 'None (0)'	System	27 Oct 2020 03:10:56
	System	27 Oct 2020 03:10:56

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-26T20:10:41', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '7ad56b0e-a38d-4f42-a12f-063b10097617' User entered 'None (0)'	System	27 Oct 2020 03:10:56
	System	27 Oct 2020 03:10:56

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-26T20:10:43', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '7ad56b0e-a38d-4f42-a12f-063b10097617' User entered 'None (0)'	System	27 Oct 2020 03:10:56
	System	27 Oct 2020 03:10:56

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-26T20:10:48', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '7ad56b0e-a38d-4f42-a12f-063b10097617' User entered 'Yes (Y)'	System	27 Oct 2020 03:10:56
	System	27 Oct 2020 03:10:56

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-26T20:10:51', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '7ad56b0e-a38d-4f42-a12f-063b10097617' User entered '26 Oct 2020 20:10'	System	27 Oct 2020 03:10:56
	System	27 Oct 2020 03:10:56

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '26 Oct 2020 12:00'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '27 Oct 2020 11:59'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	21 Oct 2020 22:13:23
User entered 'Day 7'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-27T20:09:54', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '30e93811-aa9d-48b7-9160-cd6c6184c1a4' User entered 'None (0)'	System	28 Oct 2020 03:10:20
	System	28 Oct 2020 03:10:20

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-27T20:09:56', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '30e93811-aa9d-48b7-9160-cd6c6184c1a4' User entered 'None (0)'	System	28 Oct 2020 03:10:20
	System	28 Oct 2020 03:10:20

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-27T20:09:59', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '30e93811-aa9d-48b7-9160-cd6c6184c1a4' User entered 'None (0)'	System	28 Oct 2020 03:10:20
	System	28 Oct 2020 03:10:20

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-27T20:10:03', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '30e93811-aa9d-48b7-9160-cd6c6184c1a4' User entered 'None (0)'	System	28 Oct 2020 03:10:20
	System	28 Oct 2020 03:10:20

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-27T20:10:05', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '30e93811-aa9d-48b7-9160-cd6c6184c1a4' User entered 'None (0)'	System	28 Oct 2020 03:10:20
	System	28 Oct 2020 03:10:20

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-27T20:10:08', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '30e93811-aa9d-48b7-9160-cd6c6184c1a4' User entered 'None (0)'	System	28 Oct 2020 03:10:20
	System	28 Oct 2020 03:10:20

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-27T20:10:11', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '30e93811-aa9d-48b7-9160-cd6c6184c1a4' User entered 'No (N)'	System	28 Oct 2020 03:10:20
	System	28 Oct 2020 03:10:20

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17D7A64-5924-4ED8-93E8-7643EFB52BF3)', Time: '2020-10-27T20:10:16', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '30e93811-aa9d-48b7-9160-cd6c6184c1a4' User entered '27 Oct 2020 20:10'	System	28 Oct 2020 03:10:20
	System	28 Oct 2020 03:10:20

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '27 Oct 2020 12:00'	System	21 Oct 2020 22:13:23

US3642333

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '28 Oct 2020 11:59'	System	21 Oct 2020 22:13:23

US3642333

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	(b) (4) Lindsey Woronicz (b) (4)	28 Oct 2020 17:09:18

US3642333

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '28 Oct 2020'	(b) (4) Lindsey Woronicz (b) (4)	28 Oct 2020 17:09:18

US3642333

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lindsey Woronicz (b) (4)	28 Oct 2020 17:09:18

US3642333

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Lindsey Woronicz (b) (4)	28 Oct 2020 17:09:18

US3642333

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	(b) (4) Lindsey Woronicz (b) (4)	28 Oct 2020 17:09:23

US3642333

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User entered 'I'	System	28 Oct 2020 17:09:23

US3642333

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	(b) (4) Lindsey Woronicz (b) (4)	05 Nov 2020 18:44:56

US3642333

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '5 Nov 2020'	(b) (4) Lindsey Woronicz (b) (4)	05 Nov 2020 18:44:56

US3642333

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lindsey Woronicz (b) (4)	05 Nov 2020 18:44:56

US3642333

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Lindsey Woronicz (b) (4)	05 Nov 2020 18:44:56

US3642333

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	(b) (4) Lindsey Woronicz (b) (4)	05 Nov 2020 18:45:02

US3642333

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User entered 'I'	System	05 Nov 2020 18:45:02

US3642333

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	(b) (4) Lindsey Woronicz (b) (4)	12 Nov 2020 20:23:04

US3642333

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '12 Nov 2020'	(b) (4) Lindsey Woronicz (b) (4)	12 Nov 2020 20:23:04

US3642333

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lindsey Woronicz (b) (4)	12 Nov 2020 20:23:04

US3642333

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Lindsey Woronicz (b) (4)	12 Nov 2020 20:23:04

US3642333

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	(b) (4) Lindsey Woronicz (b) (4)	12 Nov 2020 20:23:08

US3642333

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User entered 'I'	System	12 Nov 2020 20:23:08

US3642333

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:18:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4)	18 Nov 2020 22:43:56

US3642333

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '18 Nov 2020'	(b) (4) Megan Loughran (b) (4)	18 Nov 2020 22:43:56

US3642333

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Clinic (Clinic)'	(b) (4) Megan Loughran (b) (4)	18 Nov 2020 22:43:56

US3642333

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:18:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User entered 'VISIT2'	System	18 Nov 2020 22:43:56

US3642333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User accepted default value 'Pre-Dose (PREDOSE)'	Son Do (b) (4)	20 Nov 2020 16:35:43

US3642333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	Son Do (b) (4)	20 Nov 2020 16:35:43

US3642333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '18 Nov 2020'	Son Do (b) (4)	20 Nov 2020 16:35:43

US3642333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '13:15'	Son Do (b) (4)	20 Nov 2020 16:35:43

US3642333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User entered '18 Nov 2020 13:15'	System	20 Nov 2020 16:35:43

US3642333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '97.2' F	Son Do (b) (4)	20 Nov 2020 16:35:43

US3642333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Oral (Oral)'	Son Do (b) (4)	20 Nov 2020 16:35:43

US3642333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	Son Do (b) (4)	20 Nov 2020 16:35:43

US3642333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '68'	Son Do (b) (4)	20 Nov 2020 16:35:43

US3642333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User entered 'bpm'	System	20 Nov 2020 16:35:43

US3642333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '17'	Son Do (b) (4)	20 Nov 2020 16:35:43

US3642333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User entered 'breaths/min'	System	20 Nov 2020 16:35:43

US3642333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '136'	Son Do (b) (4)	20 Nov 2020 16:35:43

US3642333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User entered 'mmHg'	System	20 Nov 2020 16:35:43

US3642333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '68'	Son Do (b) (4)	20 Nov 2020 16:35:43

US3642333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User entered 'mmHg'	System	20 Nov 2020 16:35:43

US3642333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User accepted default value 'Post-Dose (POSTDOSE)'	Son Do (b) (4)	20 Nov 2020 16:35:43

US3642333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	Son Do (b) (4)	20 Nov 2020 16:35:43

US3642333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '18 Nov 2020'	Son Do (b) (4)	20 Nov 2020 16:35:43

US3642333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '15:15'	Son Do (b) (4)	20 Nov 2020 16:35:43

US3642333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User entered '18 Nov 2020 15:15'	System	20 Nov 2020 16:35:43

US3642333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '98' F	Son Do (b) (4)	20 Nov 2020 16:35:43

US3642333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Oral (Oral)'	Son Do (b) (4)	20 Nov 2020 16:35:43

US3642333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	Son Do (b) (4)	20 Nov 2020 16:35:43

US3642333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '70'	Son Do (b) (4)	20 Nov 2020 16:35:43

US3642333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User entered 'bpm'	System	20 Nov 2020 16:35:43

US3642333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '18'	Son Do (b) (4)	20 Nov 2020 16:35:43

US3642333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User entered 'breaths/min'	System	20 Nov 2020 16:35:43

US3642333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '134'	Son Do (b) (4)	20 Nov 2020 16:35:43

US3642333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User entered 'mmHg'	System	20 Nov 2020 16:35:43

US3642333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '72'	Son Do (b) (4)	20 Nov 2020 16:35:43

US3642333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User entered 'mmHg'	System	20 Nov 2020 16:35:43

US3642333

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:18:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	Son Do (b) (4)	20 Nov 2020 16:35:59

US3642333

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:18:10

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '18 Nov 2020'	Son Do (b) (4)	20 Nov 2020 16:35:59

US3642333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:10

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4)	18 Nov 2020 22:44:17

US3642333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:10

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Megan Loughran (b) (4)	18 Nov 2020 22:44:17

US3642333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Megan Loughran (b) (4)	18 Nov 2020 22:44:17

US3642333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:10

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User entered 'MRNA-1273 OR PLACEBO'	System	18 Nov 2020 22:44:17

US3642333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:10

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '18 Nov 2020'	(b) (4) Megan Loughran (b) (4)	18 Nov 2020 22:44:17

US3642333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:10

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '14:40'	(b) (4) Megan Loughran (b) (4)	18 Nov 2020 22:44:17

US3642333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:10

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User entered '18 Nov 2020 14:40'	System	18 Nov 2020 22:44:17

US3642333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:10

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Left Arm (LEFT ARM)'	(b) (4) Megan Loughran (b) (4)	18 Nov 2020 22:44:17

US3642333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:10

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User entered 'ONCE'	System	18 Nov 2020 22:44:17

US3642333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:10

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User entered 'INTRAMUSCULAR'	System	18 Nov 2020 22:44:17

US3642333

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:18:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	Son Do (b) (4)	20 Nov 2020 16:36:12

US3642333

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:18:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '18 Nov 2020'	Son Do (b) (4)	20 Nov 2020 16:36:12

US3642333

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:18:10

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '13:45'	Son Do (b) (4)	20 Nov 2020 16:36:12

US3642333

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:18:10

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User entered '18 Nov 2020 13:45'	System	20 Nov 2020 16:36:12

US3642333

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:18:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '18 Nov 2020'	Son Do (b) (4)	20 Nov 2020 16:36:28

US3642333

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:18:10

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Son Do (b) (4)	20 Nov 2020 16:36:28

US3642333

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:18:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	Son Do (b) (4)	20 Nov 2020 16:36:28

US3642333

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:18:10

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '13:30'	Son Do (b) (4)	20 Nov 2020 16:36:28

US3642333

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:18:10

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User entered '18 Nov 2020 13:30'	System	20 Nov 2020 16:36:28

US3642333

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:18:10

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User accepted default value 'Nasopharyngeal Swab 2 Son Do (NASAL2)'	(b) (4)	20 Nov 2020 16:36:28

US3642333

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:18:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)'	Son Do (b) (4)	20 Nov 2020 16:36:28

US3642333

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:18:10

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	Son Do (b) (4)	20 Nov 2020 16:36:28

US3642333

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:18:10

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User entered empty.	System	20 Nov 2020 16:36:28

US3642333

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	Son Do (b) (4)	20 Nov 2020 16:36:34

US3642333

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User entered 'I'	System	20 Nov 2020 16:36:34

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	18 Nov 2020 22:44:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-18T15:08:14', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '1eb57aa8-7666-4300-bf70-bf2a1aa5a656' User entered 'Yes (Y)'	System	18 Nov 2020 23:08:38
	System	18 Nov 2020 23:08:38

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-18T15:08:25', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '1eb57aa8-7666-4300-bf70-bf2a1aa5a656' User entered '98.0'	System	18 Nov 2020 23:08:38
	System	18 Nov 2020 23:08:38

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-18T15:08:29', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '1eb57aa8-7666-4300-bf70-bf2a1aa5a656'	System	18 Nov 2020 23:08:38
User entered 'No (N)'	System	18 Nov 2020 23:08:38

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-18T15:08:33', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '1eb57aa8-7666-4300-bf70-bf2a1aa5a656' User entered '18 Nov 2020 15:08'	System	18 Nov 2020 23:08:38
	System	18 Nov 2020 23:08:38

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '18 Nov 2020 15:00'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '18 Nov 2020 17:30'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	18 Nov 2020 22:44:17
User entered 'Day 1, after vaccination (at home)'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-18T19:06:12', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'c5bcc8ad-e9bf-46e2-89cb-b125867aab11' User entered 'Yes (Y)'	System	19 Nov 2020 03:08:48
	System	19 Nov 2020 03:08:48

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-18T19:08:32', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'c5bcc8ad-e9bf-46e2-89cb-b125867aab11' User entered '95.5'	System	19 Nov 2020 03:08:48
	System	19 Nov 2020 03:08:48

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-18T19:08:37', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'c5bcc8ad-e9bf-46e2-89cb-b125867aab11' User entered 'No (N)'	System	19 Nov 2020 03:08:48
	System	19 Nov 2020 03:08:48

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-18T19:08:40', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'c5bcc8ad-e9bf-46e2-89cb-b125867aab11' User entered '18 Nov 2020 19:08'	System	19 Nov 2020 03:08:48
	System	19 Nov 2020 03:08:48

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '18 Nov 2020 18:25'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '19 Nov 2020 11:59'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	18 Nov 2020 22:44:17
User entered 'Day 2'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:18:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-19T18:19:06', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '822b8d99-ac79-45fa-b65a-d9a0a2d2bc91' User entered 'Yes (Y)'	System	20 Nov 2020 02:19:32
	System	20 Nov 2020 02:19:32

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:18:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-19T18:19:16', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '822b8d99-ac79-45fa-b65a-d9a0a2d2bc91' User entered '96.5'	System	20 Nov 2020 02:19:32
	System	20 Nov 2020 02:19:32

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-19T18:19:20', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '822b8d99-ac79-45fa-b65a-d9a0a2d2bc91'	System	20 Nov 2020 02:19:32
User entered 'No (N)'	System	20 Nov 2020 02:19:32

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:18:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-19T18:19:27', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '822b8d99-ac79-45fa-b65a-d9a0a2d2bc91' User entered '19 Nov 2020 18:19'	System	20 Nov 2020 02:19:32
	System	20 Nov 2020 02:19:32

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '19 Nov 2020 12:00'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '20 Nov 2020 11:59'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	18 Nov 2020 22:44:17
User entered 'Day 3'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:18:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-20T18:08:10', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '5c8597b8-8699-41a1-ab3b-00127a9a8d04' User entered 'Yes (Y)'	System	21 Nov 2020 02:08:49
	System	21 Nov 2020 02:08:49

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:18:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-20T18:08:33', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '5c8597b8-8699-41a1-ab3b-00127a9a8d04' User entered '96.5'	System	21 Nov 2020 02:08:49
	System	21 Nov 2020 02:08:49

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-20T18:08:36', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '5c8597b8-8699-41a1-ab3b-00127a9a8d04'	System	21 Nov 2020 02:08:49
User entered 'No (N)'	System	21 Nov 2020 02:08:49

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:18:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-20T18:08:43', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '5c8597b8-8699-41a1-ab3b-00127a9a8d04'	System	21 Nov 2020 02:08:49
User entered '20 Nov 2020 18:08'	System	21 Nov 2020 02:08:49

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '20 Nov 2020 12:00'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '21 Nov 2020 11:59'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	18 Nov 2020 22:44:17
User entered 'Day 4'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:18:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-21T18:16:16', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '8eb7fee0-8a57-4008-991e-ece9a2788688' User entered 'Yes (Y)'	System	22 Nov 2020 02:17:02
	System	22 Nov 2020 02:17:02

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:18:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-21T18:16:26', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '8eb7fee0-8a57-4008-991e-ece9a2788688' User entered '96.7'	System	22 Nov 2020 02:17:02
	System	22 Nov 2020 02:17:02

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-21T18:16:29', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '8eb7fee0-8a57-4008-991e-ece9a2788688' User entered 'No (N)'	System	22 Nov 2020 02:17:02
	System	22 Nov 2020 02:17:02

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:18:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-21T18:16:32', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '8eb7fee0-8a57-4008-991e-ece9a2788688' User entered '21 Nov 2020 18:16'	System	22 Nov 2020 02:17:02
	System	22 Nov 2020 02:17:02

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '21 Nov 2020 12:00'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '22 Nov 2020 11:59'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	18 Nov 2020 22:44:17
User entered 'Day 5'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:18:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-22T19:19:08', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '6ad6ec10-c8bc-431f-b19f-c0427b8daadb' User entered 'Yes (Y)'	System	23 Nov 2020 03:19:30
	System	23 Nov 2020 03:19:30

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:18:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-22T19:19:17', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '6ad6ec10-c8bc-431f-b19f-c0427b8daadb' User entered '96.7'	System	23 Nov 2020 03:19:30
	System	23 Nov 2020 03:19:30

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-22T19:19:22', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '6ad6ec10-c8bc-431f-b19f-c0427b8daadb' User entered 'No (N)'	System	23 Nov 2020 03:19:30
	System	23 Nov 2020 03:19:30

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:18:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-22T19:19:27', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '6ad6ec10-c8bc-431f-b19f-c0427b8daadb' User entered '22 Nov 2020 19:19'	System	23 Nov 2020 03:19:30
	System	23 Nov 2020 03:19:30

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '22 Nov 2020 12:00'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '23 Nov 2020 11:59'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	18 Nov 2020 22:44:17
User entered 'Day 6'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:18:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:18:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:18:10

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:18:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '23 Nov 2020 12:00'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '24 Nov 2020 11:59'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	18 Nov 2020 22:44:17
User entered 'Day 7'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:18:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-24T19:15:01', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'c524580a-c76a-4991-b388-0605d3522abf' User entered 'Yes (Y)'	System	25 Nov 2020 03:15:22
	System	25 Nov 2020 03:15:22

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:18:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-24T19:15:11', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'c524580a-c76a-4991-b388-0605d3522abf' User entered '96.5'	System	25 Nov 2020 03:15:22
	System	25 Nov 2020 03:15:22

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-24T19:15:15', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'c524580a-c76a-4991-b388-0605d3522abf' User entered 'No (N)'	System	25 Nov 2020 03:15:22
	System	25 Nov 2020 03:15:22

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:18:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-24T19:15:18', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'c524580a-c76a-4991-b388-0605d3522abf' User entered '24 Nov 2020 19:15'	System	25 Nov 2020 03:15:22
	System	25 Nov 2020 03:15:22

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '24 Nov 2020 12:00'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '25 Nov 2020 11:59'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	18 Nov 2020 22:44:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-18T15:06:26', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '44e8617d-cd50-4411-a628-0ba6085d246d' User entered 'None (1)'	System	18 Nov 2020 23:06:55
	System	18 Nov 2020 23:06:55

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-18T15:06:34', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '44e8617d-cd50-4411-a628-0ba6085d246d' User entered 'No (N)'	System	18 Nov 2020 23:06:55
	System	18 Nov 2020 23:06:55

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-18T15:06:38', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '44e8617d-cd50-4411-a628-0ba6085d246d' User entered 'No (N)'	System	18 Nov 2020 23:06:55
	System	18 Nov 2020 23:06:55

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-18T15:06:43', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '44e8617d-cd50-4411-a628-0ba6085d246d' User entered 'None (1)'	System	18 Nov 2020 23:06:55
	System	18 Nov 2020 23:06:55

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-18T15:06:51', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '44e8617d-cd50-4411-a628-0ba6085d246d' User entered '18 Nov 2020 15:06'	System	18 Nov 2020 23:06:55
	System	18 Nov 2020 23:06:55

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '18 Nov 2020 15:00'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '18 Nov 2020 17:30'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	18 Nov 2020 22:44:17
User entered 'Day 1, after vaccination (at home)'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-18T19:08:49', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '8345e194-6e92-4c08-9b06-1c110600a08f'	System	19 Nov 2020 03:09:19
User entered 'Does not interfere with activity (2)'	System	19 Nov 2020 03:09:19

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-18T19:08:53', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '8345e194-6e92-4c08-9b06-1c110600a08f' User entered 'No (N)'	System	19 Nov 2020 03:09:19
	System	19 Nov 2020 03:09:19

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-18T19:08:58', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '8345e194-6e92-4c08-9b06-1c110600a08f' User entered 'No (N)'	System	19 Nov 2020 03:09:19
	System	19 Nov 2020 03:09:19

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-18T19:09:02', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '8345e194-6e92-4c08-9b06-1c110600a08f' User entered 'None (1)'	System	19 Nov 2020 03:09:19
	System	19 Nov 2020 03:09:19

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-18T19:09:14', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '8345e194-6e92-4c08-9b06-1c110600a08f' User entered '18 Nov 2020 19:09'	System	19 Nov 2020 03:09:19
	System	19 Nov 2020 03:09:19

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '18 Nov 2020 18:25'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '19 Nov 2020 11:59'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	18 Nov 2020 22:44:17
User entered 'Day 2'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:18:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-19T18:19:34', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '7d78a1ac-3cac-42dd-9968-0ae38b0161d1' User entered 'None (1)'	System	20 Nov 2020 02:19:57
	System	20 Nov 2020 02:19:57

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:18:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-19T18:19:39', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '7d78a1ac-3cac-42dd-9968-0ae38b0161d1' User entered 'No (N)'	System	20 Nov 2020 02:19:57
	System	20 Nov 2020 02:19:57

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-19T18:19:43', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '7d78a1ac-3cac-42dd-9968-0ae38b0161d1' User entered 'No (N)'	System	20 Nov 2020 02:19:57
	System	20 Nov 2020 02:19:57

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:18:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-19T18:19:49', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '7d78a1ac-3cac-42dd-9968-0ae38b0161d1' User entered 'None (1)'	System	20 Nov 2020 02:19:57
	System	20 Nov 2020 02:19:57

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:18:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-19T18:19:55', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '7d78a1ac-3cac-42dd-9968-0ae38b0161d1' User entered '19 Nov 2020 18:19'	System	20 Nov 2020 02:19:57
	System	20 Nov 2020 02:19:57

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '19 Nov 2020 12:00'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '20 Nov 2020 11:59'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	18 Nov 2020 22:44:17
User entered 'Day 3'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:18:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-20T18:08:49', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '2853a3a3-517e-425f-b8d9-73886fe02fa9' User entered 'None (1)'	System	21 Nov 2020 02:09:06
	System	21 Nov 2020 02:09:06

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:18:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-20T18:08:53', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '2853a3a3-517e-425f-b8d9-73886fe02fa9' User entered 'No (N)'	System	21 Nov 2020 02:09:06
	System	21 Nov 2020 02:09:06

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-20T18:08:55', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '2853a3a3-517e-425f-b8d9-73886fe02fa9' User entered 'No (N)'	System	21 Nov 2020 02:09:06
	System	21 Nov 2020 02:09:06

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:18:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-20T18:09:00', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '2853a3a3-517e-425f-b8d9-73886fe02fa9' User entered 'None (1)'	System	21 Nov 2020 02:09:06
	System	21 Nov 2020 02:09:06

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:18:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-20T18:09:05', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '2853a3a3-517e-425f-b8d9-73886fe02fa9' User entered '20 Nov 2020 18:09'	System	21 Nov 2020 02:09:06
	System	21 Nov 2020 02:09:06

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '20 Nov 2020 12:00'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '21 Nov 2020 11:59'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	18 Nov 2020 22:44:17
User entered 'Day 4'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:18:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-21T18:16:48', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'dd7825b9-7ccb-45d1-927e-f23771d6a94f' User entered 'None (1)'	System	22 Nov 2020 02:17:09
	System	22 Nov 2020 02:17:09

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:18:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-21T18:16:52', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'dd7825b9-7ccb-45d1-927e-f23771d6a94f' User entered 'No (N)'	System	22 Nov 2020 02:17:09
	System	22 Nov 2020 02:17:09

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-21T18:16:56', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'dd7825b9-7ccb-45d1-927e-f23771d6a94f' User entered 'No (N)'	System	22 Nov 2020 02:17:09
	System	22 Nov 2020 02:17:09

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:18:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-21T18:16:59', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'dd7825b9-7ccb-45d1-927e-f23771d6a94f' User entered 'None (1)'	System	22 Nov 2020 02:17:09
	System	22 Nov 2020 02:17:09

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:18:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-21T18:17:03', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'dd7825b9-7ccb-45d1-927e-f23771d6a94f' User entered '21 Nov 2020 18:17'	System	22 Nov 2020 02:17:09
	System	22 Nov 2020 02:17:09

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '21 Nov 2020 12:00'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '22 Nov 2020 11:59'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	18 Nov 2020 22:44:17
User entered 'Day 5'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:18:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-22T19:19:33', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '209e8083-0fa5-4f45-bffe-3fb612229174' User entered 'None (1)'	System	23 Nov 2020 03:19:54
	System	23 Nov 2020 03:19:54

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:18:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-22T19:19:39', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '209e8083-0fa5-4f45-bffe-3fb612229174' User entered 'No (N)'	System	23 Nov 2020 03:19:54
	System	23 Nov 2020 03:19:54

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-22T19:19:44', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '209e8083-0fa5-4f45-bffe-3fb612229174' User entered 'No (N)'	System	23 Nov 2020 03:19:54
	System	23 Nov 2020 03:19:54

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:18:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-22T19:19:48', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '209e8083-0fa5-4f45-bffe-3fb612229174' User entered 'None (1)'	System	23 Nov 2020 03:19:54
	System	23 Nov 2020 03:19:54

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:18:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-22T19:19:52', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '209e8083-0fa5-4f45-bffe-3fb612229174' User entered '22 Nov 2020 19:19'	System	23 Nov 2020 03:19:54
	System	23 Nov 2020 03:19:54

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '22 Nov 2020 12:00'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '23 Nov 2020 11:59'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	18 Nov 2020 22:44:17
User entered 'Day 6'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:18:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:18:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:18:10

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:18:10

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:18:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:18:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '23 Nov 2020 12:00'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '24 Nov 2020 11:59'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	18 Nov 2020 22:44:17
User entered 'Day 7'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:18:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-24T19:24:35', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '6378a5e0-2337-421b-a92f-b34ae952ba67' User entered 'None (1)'	System	25 Nov 2020 03:24:56
	System	25 Nov 2020 03:24:56

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:18:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-24T19:24:41', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '6378a5e0-2337-421b-a92f-b34ae952ba67' User entered 'No (N)'	System	25 Nov 2020 03:24:56
	System	25 Nov 2020 03:24:56

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-24T19:24:44', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '6378a5e0-2337-421b-a92f-b34ae952ba67' User entered 'No (N)'	System	25 Nov 2020 03:24:56
	System	25 Nov 2020 03:24:56

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:18:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-24T19:24:48', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '6378a5e0-2337-421b-a92f-b34ae952ba67' User entered 'None (1)'	System	25 Nov 2020 03:24:56
	System	25 Nov 2020 03:24:56

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:18:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-24T19:24:53', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '6378a5e0-2337-421b-a92f-b34ae952ba67' User entered '24 Nov 2020 19:24'	System	25 Nov 2020 03:24:56
	System	25 Nov 2020 03:24:56

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '24 Nov 2020 12:00'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '25 Nov 2020 11:59'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	18 Nov 2020 22:44:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-18T15:06:59', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '633e39c4-eb80-45df-9306-123118b2d929' User entered 'None (0)'	System	18 Nov 2020 23:07:38
	System	18 Nov 2020 23:07:38

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-18T15:07:02', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '633e39c4-eb80-45df-9306-123118b2d929' User entered 'None (0)'	System	18 Nov 2020 23:07:38
	System	18 Nov 2020 23:07:38

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-18T15:07:09', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '633e39c4-eb80-45df-9306-123118b2d929' User entered 'None (0)'	System	18 Nov 2020 23:07:38
	System	18 Nov 2020 23:07:38

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-18T15:07:13', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '633e39c4-eb80-45df-9306-123118b2d929' User entered 'None (0)'	System	18 Nov 2020 23:07:38
	System	18 Nov 2020 23:07:38

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-18T15:07:18', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '633e39c4-eb80-45df-9306-123118b2d929' User entered 'None (0)'	System	18 Nov 2020 23:07:38
	System	18 Nov 2020 23:07:38

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-18T15:07:21', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '633e39c4-eb80-45df-9306-123118b2d929' User entered 'None (0)'	System	18 Nov 2020 23:07:38
	System	18 Nov 2020 23:07:38

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-18T15:07:26', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '633e39c4-eb80-45df-9306-123118b2d929'	System	18 Nov 2020 23:07:38
User entered 'Yes (Y)'	System	18 Nov 2020 23:07:38

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-18T15:07:31', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '633e39c4-eb80-45df-9306-123118b2d929' User entered '18 Nov 2020 15:07'	System	18 Nov 2020 23:07:38
	System	18 Nov 2020 23:07:38

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '18 Nov 2020 15:00'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '18 Nov 2020 17:30'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	18 Nov 2020 22:44:17
User entered 'Day 1, after vaccination (at home)'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-18T19:09:22', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'fd9a24fa-e198-4ffa-b995-5cdabb7317c7'	System	19 Nov 2020 03:09:49
User entered 'None (0)'	System	19 Nov 2020 03:09:49

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-18T19:09:25', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'fd9a24fa-e198-4ffa-b995-5cdabb7317c7'	System	19 Nov 2020 03:09:49
User entered 'None (0)'	System	19 Nov 2020 03:09:49

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-18T19:09:28', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'fd9a24fa-e198-4ffa-b995-5cdabb7317c7'	System	19 Nov 2020 03:09:49
User entered 'None (0)'	System	19 Nov 2020 03:09:49

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-18T19:09:32', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'fd9a24fa-e198-4ffa-b995-5cdabb7317c7'	System	19 Nov 2020 03:09:49
User entered 'None (0)'	System	19 Nov 2020 03:09:49

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-18T19:09:35', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'fd9a24fa-e198-4ffa-b995-5cdabb7317c7'	System	19 Nov 2020 03:09:49
User entered 'None (0)'	System	19 Nov 2020 03:09:49

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-18T19:09:37', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'fd9a24fa-e198-4ffa-b995-5cdabb7317c7'	System	19 Nov 2020 03:09:49
User entered 'None (0)'	System	19 Nov 2020 03:09:49

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-18T19:09:41', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'fd9a24fa-e198-4ffa-b995-5cdabb7317c7'	System	19 Nov 2020 03:09:49
User entered 'Yes (Y)'	System	19 Nov 2020 03:09:49

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-18T19:09:45', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'fd9a24fa-e198-4ffa-b995-5cdabb7317c7'	System	19 Nov 2020 03:09:49
User entered '18 Nov 2020 19:09'	System	19 Nov 2020 03:09:49

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '18 Nov 2020 18:25'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '19 Nov 2020 11:59'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	18 Nov 2020 22:44:17
User entered 'Day 2'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-19T18:20:02', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'dc64a74d-3422-4c0f-9e2a-46f8926bb7a6' User entered 'None (0)'	System	20 Nov 2020 02:20:39
	System	20 Nov 2020 02:20:39

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-19T18:20:05', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'dc64a74d-3422-4c0f-9e2a-46f8926bb7a6' User entered 'None (0)'	System	20 Nov 2020 02:20:39
	System	20 Nov 2020 02:20:39

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-19T18:20:09', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'dc64a74d-3422-4c0f-9e2a-46f8926bb7a6' User entered 'None (0)'	System	20 Nov 2020 02:20:39
	System	20 Nov 2020 02:20:39

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-19T18:20:12', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'dc64a74d-3422-4c0f-9e2a-46f8926bb7a6' User entered 'None (0)'	System	20 Nov 2020 02:20:39
	System	20 Nov 2020 02:20:39

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-19T18:20:15', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'dc64a74d-3422-4c0f-9e2a-46f8926bb7a6' User entered 'None (0)'	System	20 Nov 2020 02:20:39
	System	20 Nov 2020 02:20:39

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-19T18:20:18', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'dc64a74d-3422-4c0f-9e2a-46f8926bb7a6' User entered 'None (0)'	System	20 Nov 2020 02:20:39
	System	20 Nov 2020 02:20:39

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-19T18:20:27', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'dc64a74d-3422-4c0f-9e2a-46f8926bb7a6' User entered 'No (N)'	System	20 Nov 2020 02:20:39
	System	20 Nov 2020 02:20:39

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-19T18:20:35', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'dc64a74d-3422-4c0f-9e2a-46f8926bb7a6' User entered '19 Nov 2020 18:20'	System	20 Nov 2020 02:20:39
	System	20 Nov 2020 02:20:39

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '19 Nov 2020 12:00'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '20 Nov 2020 11:59'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	18 Nov 2020 22:44:17
User entered 'Day 3'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-20T18:09:11', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'f668e87b-829a-40b1-8471-0996bdc394c5' User entered 'None (0)'	System	21 Nov 2020 02:09:34
	System	21 Nov 2020 02:09:34

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-20T18:09:13', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'f668e87b-829a-40b1-8471-0996bdc394c5' User entered 'None (0)'	System	21 Nov 2020 02:09:34
	System	21 Nov 2020 02:09:34

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-20T18:09:15', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'f668e87b-829a-40b1-8471-0996bdc394c5' User entered 'None (0)'	System	21 Nov 2020 02:09:34
	System	21 Nov 2020 02:09:34

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-20T18:09:18', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'f668e87b-829a-40b1-8471-0996bdc394c5' User entered 'None (0)'	System	21 Nov 2020 02:09:34
	System	21 Nov 2020 02:09:34

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-20T18:09:21', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'f668e87b-829a-40b1-8471-0996bdc394c5' User entered 'None (0)'	System	21 Nov 2020 02:09:34
	System	21 Nov 2020 02:09:34

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-20T18:09:23', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'f668e87b-829a-40b1-8471-0996bdc394c5' User entered 'None (0)'	System	21 Nov 2020 02:09:34
	System	21 Nov 2020 02:09:34

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-20T18:09:27', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'f668e87b-829a-40b1-8471-0996bdc394c5' User entered 'No (N)'	System	21 Nov 2020 02:09:34
	System	21 Nov 2020 02:09:34

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-20T18:09:31', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'f668e87b-829a-40b1-8471-0996bdc394c5' User entered '20 Nov 2020 18:09'	System	21 Nov 2020 02:09:34
	System	21 Nov 2020 02:09:34

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '20 Nov 2020 12:00'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '21 Nov 2020 11:59'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	18 Nov 2020 22:44:17
User entered 'Day 4'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-21T18:17:10', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'fefa25cc-a68c-4c99-849f-94adc44bf635'	System	22 Nov 2020 02:17:37
User entered 'None (0)'	System	22 Nov 2020 02:17:37

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-21T18:17:12', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'fefa25cc-a68c-4c99-849f-94adc44bf635'	System	22 Nov 2020 02:17:37
User entered 'None (0)'	System	22 Nov 2020 02:17:37

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-21T18:17:15', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'fefa25cc-a68c-4c99-849f-94adc44bf635'	System	22 Nov 2020 02:17:37
User entered 'None (0)'	System	22 Nov 2020 02:17:37

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-21T18:17:18', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'fefa25cc-a68c-4c99-849f-94adc44bf635' User entered 'None (0)'	System	22 Nov 2020 02:17:37
	System	22 Nov 2020 02:17:37

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-21T18:17:21', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'fefa25cc-a68c-4c99-849f-94adc44bf635' User entered 'None (0)'	System	22 Nov 2020 02:17:37
	System	22 Nov 2020 02:17:37

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-21T18:17:24', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'fefa25cc-a68c-4c99-849f-94adc44bf635' User entered 'None (0)'	System	22 Nov 2020 02:17:37
	System	22 Nov 2020 02:17:37

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-21T18:17:28', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'fefa25cc-a68c-4c99-849f-94adc44bf635'	System	22 Nov 2020 02:17:37
User entered 'No (N)'	System	22 Nov 2020 02:17:37

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-21T18:17:32', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: 'fefa25cc-a68c-4c99-849f-94adc44bf635'	System	22 Nov 2020 02:17:37
User entered '21 Nov 2020 18:17'	System	22 Nov 2020 02:17:37

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '21 Nov 2020 12:00'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '22 Nov 2020 11:59'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	18 Nov 2020 22:44:17
User entered 'Day 5'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-22T19:19:58', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '26dd494c-3e2f-4a72-ac5b-61150760dbdc' User entered 'None (0)'	System	23 Nov 2020 03:20:25
	System	23 Nov 2020 03:20:25

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-22T19:20:01', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '26dd494c-3e2f-4a72-ac5b-61150760dbdc' User entered 'None (0)'	System	23 Nov 2020 03:20:25
	System	23 Nov 2020 03:20:25

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-22T19:20:04', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '26dd494c-3e2f-4a72-ac5b-61150760dbdc' User entered 'None (0)'	System	23 Nov 2020 03:20:25
	System	23 Nov 2020 03:20:25

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-22T19:20:09', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '26dd494c-3e2f-4a72-ac5b-61150760dbdc' User entered 'None (0)'	System	23 Nov 2020 03:20:25
	System	23 Nov 2020 03:20:25

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-22T19:20:14', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '26dd494c-3e2f-4a72-ac5b-61150760dbdc' User entered 'None (0)'	System	23 Nov 2020 03:20:25
	System	23 Nov 2020 03:20:25

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-22T19:20:17', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '26dd494c-3e2f-4a72-ac5b-61150760dbdc' User entered 'None (0)'	System	23 Nov 2020 03:20:25
	System	23 Nov 2020 03:20:25

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-22T19:20:19', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '26dd494c-3e2f-4a72-ac5b-61150760dbdc' User entered 'No (N)'	System	23 Nov 2020 03:20:25
	System	23 Nov 2020 03:20:25

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-22T19:20:23', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '26dd494c-3e2f-4a72-ac5b-61150760dbdc' User entered '22 Nov 2020 19:20'	System	23 Nov 2020 03:20:25
	System	23 Nov 2020 03:20:25

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '22 Nov 2020 12:00'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '23 Nov 2020 11:59'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	18 Nov 2020 22:44:17
User entered 'Day 6'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '23 Nov 2020 12:00'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '24 Nov 2020 11:59'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
Data entry locked.	System	18 Nov 2020 22:44:17
User entered 'Day 7'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-24T19:24:59', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '5cbe800e-f62e-4633-9401-f5923658d36e' User entered 'None (0)'	System	25 Nov 2020 03:26:28
	System	25 Nov 2020 03:26:28

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-24T19:25:02', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '5cbe800e-f62e-4633-9401-f5923658d36e' User entered 'None (0)'	System	25 Nov 2020 03:26:28
	System	25 Nov 2020 03:26:28

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-24T19:25:07', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '5cbe800e-f62e-4633-9401-f5923658d36e' User entered 'None (0)'	System	25 Nov 2020 03:26:28
	System	25 Nov 2020 03:26:28

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-24T19:25:10', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '5cbe800e-f62e-4633-9401-f5923658d36e' User entered 'None (0)'	System	25 Nov 2020 03:26:28
	System	25 Nov 2020 03:26:28

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-24T19:25:17', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '5cbe800e-f62e-4633-9401-f5923658d36e' User entered 'None (0)'	System	25 Nov 2020 03:26:28
	System	25 Nov 2020 03:26:28

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-24T19:25:20', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '5cbe800e-f62e-4633-9401-f5923658d36e' User entered 'None (0)'	System	25 Nov 2020 03:26:28
	System	25 Nov 2020 03:26:28

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-24T19:25:29', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '5cbe800e-f62e-4633-9401-f5923658d36e' User entered 'No (N)'	System	25 Nov 2020 03:26:28
	System	25 Nov 2020 03:26:28

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (864693DD-51D4-4602-9955-D69C99366C5F)', Time: '2020-11-24T19:26:25', User OID: 'PatientReportedOutcome (US3642333)', ODM File OID: '5cbe800e-f62e-4633-9401-f5923658d36e' User entered '24 Nov 2020 19:26'	System	25 Nov 2020 03:26:28
	System	25 Nov 2020 03:26:28

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '24 Nov 2020 12:00'	System	18 Nov 2020 22:44:17

US3642333

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:45:56
User entered '25 Nov 2020 11:59'	System	18 Nov 2020 22:44:17

US3642333

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	(b) (4) Lindsey Woronicz (b) (4)	25 Nov 2020 20:16:46

US3642333

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '25 Nov 2020'	(b) (4) Lindsey Woronicz (b) (4)	25 Nov 2020 20:16:46

US3642333

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lindsey Woronicz (b) (4)	25 Nov 2020 20:16:46

US3642333

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Lindsey Woronicz (b) (4)	25 Nov 2020 20:16:46

US3642333

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	(b) (4) Lindsey Woronicz (b) (4)	25 Nov 2020 20:16:52

US3642333

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User entered 'I'	System	25 Nov 2020 20:16:52

US3642333

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	(b) (4) Lindsey Woronicz (b) (4)	02 Dec 2020 22:09:11

US3642333

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '2 Dec 2020'	(b) (4) Lindsey Woronicz (b) (4)	02 Dec 2020 22:09:11

US3642333

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lindsey Woronicz (b) (4)	02 Dec 2020 22:09:11

US3642333

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Lindsey Woronicz (b) (4)	02 Dec 2020 22:09:11

US3642333

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	(b) (4) Lindsey Woronicz (b) (4)	02 Dec 2020 22:09:04

US3642333

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User entered 'I'	System	02 Dec 2020 22:09:04

US3642333

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	Jennifer Morales (b) (4)	10 Dec 2020 19:06:47

US3642333

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '10 Dec 2020'	Jennifer Morales (b) (4)	10 Dec 2020 19:06:47

US3642333

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jennifer Morales (b) (4)	10 Dec 2020 19:06:47

US3642333

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	Jennifer Morales (b) (4)	10 Dec 2020 19:06:47

US3642333

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	Jennifer Morales (b) (4)	10 Dec 2020 19:06:53

US3642333

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User entered 'I'	System	10 Dec 2020 19:06:53

US3642333

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:18:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:23
User entered 'Yes (Y)'	Son Do (b) (4)	18 Dec 2020 17:02:53

US3642333

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:23
User entered '16 Dec 2020'	Son Do (b) (4)	18 Dec 2020 17:02:53

US3642333

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:23
User entered 'Clinic (Clinic)'	Son Do (b) (4)	18 Dec 2020 17:02:53

US3642333

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:18:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User entered 'VISIT3'	System	18 Dec 2020 17:02:53

US3642333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:23
User entered 'Yes (Y)'	Son Do (b) (4)	18 Dec 2020 17:03:16

US3642333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:23
User entered '16 Dec 2020'	Son Do (b) (4)	18 Dec 2020 17:03:16

US3642333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:23
User entered '13:17'	Son Do (b) (4)	18 Dec 2020 17:03:16

US3642333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User entered '16 Dec 2020 13:17'	System	18 Dec 2020 17:03:16

US3642333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:23
User entered '98.3' F	Son Do (b) (4)	18 Dec 2020 17:03:16

US3642333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:23
User entered 'Oral (Oral)'	Son Do (b) (4)	18 Dec 2020 17:03:16

US3642333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:23
User entered empty.	Son Do (b) (4)	18 Dec 2020 17:03:16

US3642333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:23
User entered '79'	Son Do (b) (4)	18 Dec 2020 17:03:16

US3642333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User entered 'bpm'	System	18 Dec 2020 17:03:16

US3642333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:23
User entered '16'	Son Do (b) (4)	18 Dec 2020 17:03:16

US3642333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User entered 'breaths/min'	System	18 Dec 2020 17:03:16

US3642333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:23
User entered '143'	Son Do (b) (4)	18 Dec 2020 17:03:16

US3642333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User entered 'mmHg'	System	18 Dec 2020 17:03:16

US3642333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:23
User entered '80'	Son Do (b) (4)	18 Dec 2020 17:03:16

US3642333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User entered 'mmHg'	System	18 Dec 2020 17:03:16

US3642333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:10

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28

US3642333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:10

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28

US3642333

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:18:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:23
User entered 'No (N)'	Son Do (b) (4)	18 Dec 2020 17:03:22

US3642333

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:18:10

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:23
User entered empty.	Son Do (b) (4)	18 Dec 2020 17:03:22

US3642333

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:18:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	Son Do (b) (4)	18 Dec 2020 17:03:34

US3642333

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:18:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '16 Dec 2020'	Son Do (b) (4)	18 Dec 2020 17:03:34

US3642333

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:18:10

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '13:36'	Son Do (b) (4)	18 Dec 2020 17:03:34

US3642333

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:18:10

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User entered '16 Dec 2020 13:36'	System	18 Dec 2020 17:03:34

US3642333

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	Son Do (b) (4)	18 Dec 2020 17:03:39

US3642333

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:28
User entered '1'	System	18 Dec 2020 17:03:39

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '18 Nov 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '22 Nov 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '25 Nov 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '29 Nov 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '02 Dec 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '06 Dec 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '09 Dec 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '13 Dec 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '16 Dec 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '20 Dec 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '23 Dec 2022 00:01'	System	20 Nov 2020 13:25:58

US3642333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:25:58
Amendment Manager: User entered '27 Dec 2022 23:59'	System	20 Nov 2020 13:25:58

US3642333

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Lindsey Woronicz (b) (4)	19 Jan 2021 20:11:46
User entered 'Yes (Y)'	Jennifer Morales (b) (4)	15 Jan 2021 01:12:57
	(b) (4)	

US3642333

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty; reason for change Data Entry Error	(b) (4)	
	Lindsey Woronicz (b) (4)	19 Jan 2021 20:11:46
User entered '14 Jan 2021'	Jennifer Morales (b) (4)	15 Jan 2021 01:12:57
	(b) (4)	

US3642333

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty; reason for change Data Entry Error	(b) (4)	
	Lindsey Woronicz (b) (4)	19 Jan 2021 20:11:46
User entered 'Contact Made (CONTACT MADE)'	Jennifer Morales (b) (4)	15 Jan 2021 01:12:57
	(b) (4)	

US3642333

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	Jennifer Morales (b) (4)	15 Jan 2021 01:12:57

US3642333

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	Jennifer Morales (b) (4)	15 Jan 2021 01:13:02

US3642333

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:48:18
User entered 'I'	System	15 Jan 2021 01:13:02

US3642333

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:45
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:15:49
User entered 'Yes (Y)'	Jennifer Morales (b) (4)	18 Feb 2021 21:06:28

US3642333

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:45
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:15:49
User entered '18 Feb 2021'	Jennifer Morales (b) (4)	18 Feb 2021 21:06:28

US3642333

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:45
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:15:49
User entered 'Contact Not Made (CONTACT NOT MADE)'	Jennifer Morales (b) (4)	18 Feb 2021 21:06:28

US3642333

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:45
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:15:49
User entered 'ATTEMPT MADE ON 18FEB2021 LEFT VOICE MESSAGE TO CALL (b) (6) '	(b) (4) Jennifer Morales (b) (4) (b) (4)	18 Feb 2021 21:06:28

US3642333

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:45
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:15:49
User entered 'Yes (Y)'	Jennifer Morales (b) (4)	18 Feb 2021 21:06:39

US3642333

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:45
User entered 'I'	System	18 Feb 2021 21:06:39

US3642333

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:45
User signature succeeded.	Stephen Spector (b) (4)	20 Mar 2021 00:04:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:11:10

US3642333

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:45
User signature succeeded.	Stephen Spector (b) (4)	20 Mar 2021 00:04:40
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:11:10

US3642333

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:45
User signature succeeded.	Stephen Spector (b) (4)	20 Mar 2021 00:04:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:11:10

US3642333

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:45
User signature succeeded.	Stephen Spector (b) (4)	20 Mar 2021 00:04:40
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 17:11:10

US3642333

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:45
User signature succeeded.	Stephen Spector (b) (4)	20 Mar 2021 00:04:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:11:17

US3642333

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:45
User entered 'I'	System	16 Mar 2021 17:11:17

US3642333

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:08:37
	(b) (4)	
User entered 'Yes (Y)'	Jennifer Morales (b) (4)	14 Apr 2021 19:39:37
	(b) (4)	

US3642333

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:08:37
	(b) (4)	
User entered '14 Apr 2021'	Jennifer Morales (b) (4)	14 Apr 2021 19:39:37
	(b) (4)	

US3642333

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:08:37
User entered 'Contact Made (CONTACT MADE)'	Jennifer Morales (b) (4)	14 Apr 2021 19:39:37

US3642333

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:08:37
	(b) (4)	
User entered empty.	Jennifer Morales (b) (4)	14 Apr 2021 19:39:37
	(b) (4)	

US3642333

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:08:37
	(b) (4)	
User entered 'Yes (Y)'	Jennifer Morales (b) (4)	14 Apr 2021 19:39:43
	(b) (4)	

US3642333

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:10

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 19:39:43

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:18:10

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:15:56
User closed query 'Please verify and complete symptom log as required.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 10:57:02
Query 'Please verify and complete symptom log as required.' answered with 'Phone contact was made with subject. However, he declined answering questions tp symptom log. Illness visit was not completed. Therefore, No data is available by subject for symptom log.' (Site from CRA).	Nancy Tang (b) (4)	14 Apr 2021 16:57:36
User opened query 'Please verify and complete symptom log as required.' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 13:47:49
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '19 Dec 2020'	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 18:04:35

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:18:10

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:15:56
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '08:00'	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 18:04:35

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:18:10

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:15:56
User entered '19 Dec 2020 08:00'	System	02 Feb 2021 18:04:35

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:18:10

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:15:56
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Safety Call (Safety Call)'	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 18:04:35

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:18:10

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:15:56
User closed query 'Per CDM: Per sponsor review, subject reports symptoms of SARS-COV-2. However symptom log is incomplete. Please review and update.' (Site from DM).		08 Mar 2021 04:16:29
Query 'Per CDM: Per sponsor review, subject reports symptoms of SARS-COV-2. However symptom log is incomplete. Please review and update.' answered with 'PATIENT IS EXTREMELY DIFFICULT TO CONTACT AND POOR HISTORIAN/UNABLE TO GIVE US SPECIFIC DETIALS ON SYMPTOMS OR DATES OF SYMPTOMS. STUDY STAFF CONTINUE TO ATTEMPT TO CONTACT HIM AND HIS EMERGENCY CONTACT FREQUENTLY IN AN ATTEMPT TO COLLECT MORE DATA REGARDING HIS COVID-19 CASE. STUDY STAFF HAS BEEN UNABLE TO COLLECT MEDICAL RECORDS FROM ENSENADA MEXICO AT THIS TIME. ' (Site from DM).	Colleen McLellan (b) (4)	05 Mar 2021 16:53:29
User opened query 'Per CDM: Per sponsor review, subject reports symptoms of SARS-COV-2. However symptom log is incomplete. Please review and update.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 18:32:22
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 18:04:35

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:18:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:05
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:36:32
User entered empty.	(b) (4) Benjamin Hull (b) (4) (b) (4)	31 Mar 2021 22:45:50

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:18:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:05
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:36:32
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 22:46:23
User entered '19 Dec 2020' reason for change: Data Entry Error	System	31 Mar 2021 22:46:23
User opened query 'Data is required. Please complete.' (Site from System).	Benjamin Hull (b) (4)	31 Mar 2021 22:46:23
User entered empty.	(b) (4)	
	System	31 Mar 2021 22:45:50
	Benjamin Hull (b) (4)	31 Mar 2021 22:45:50
	(b) (4)	

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:18:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:05
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:36:32
User entered 'I'	(b) (4) Benjamin Hull (b) (4) (b) (4)	31 Mar 2021 22:45:50

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:18:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:05
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:36:32
User entered empty.	(b) (4) Benjamin Hull (b) (4) (b) (4)	31 Mar 2021 22:45:50

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:18:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:05
User entered empty.	System	31 Mar 2021 22:45:50

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:18:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:05
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:36:32
User entered empty.	(b) (4) Benjamin Hull (b) (4) (b) (4)	31 Mar 2021 22:45:50

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:18:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:05
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:36:32
User entered empty.	(b) (4) Benjamin Hull (b) (4) (b) (4)	31 Mar 2021 22:45:50

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:18:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:05
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:36:32
User entered empty.	(b) (4) Benjamin Hull (b) (4) (b) (4)	31 Mar 2021 22:45:50

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:18:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:05
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:36:32
User entered empty.	(b) (4) Benjamin Hull (b) (4) (b) (4)	31 Mar 2021 22:45:50

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:18:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:05
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:36:32
User entered empty.	(b) (4) Benjamin Hull (b) (4) (b) (4)	31 Mar 2021 22:45:50

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:18:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:05
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:36:32
User entered empty.	(b) (4) Benjamin Hull (b) (4)	31 Mar 2021 22:45:50

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:18:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:05
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:36:32
User entered empty.	(b) (4) Benjamin Hull (b) (4) (b) (4)	31 Mar 2021 22:45:50

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:18:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:05
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:36:32
User entered empty.	(b) (4) Benjamin Hull (b) (4) (b) (4)	31 Mar 2021 22:45:50

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:18:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:05
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:36:32
User entered empty.	(b) (4) Benjamin Hull (b) (4) (b) (4)	31 Mar 2021 22:45:50

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:18:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:05
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:36:32
User entered empty.	(b) (4) Benjamin Hull (b) (4) (b) (4)	31 Mar 2021 22:45:50

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:18:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:05
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:36:32
User entered empty.	(b) (4) Benjamin Hull (b) (4) (b) (4)	31 Mar 2021 22:45:50

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:18:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:05
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:36:32
User entered empty.	(b) (4) Benjamin Hull (b) (4) (b) (4)	31 Mar 2021 22:45:50

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:18:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:05
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:36:32
User entered empty.	(b) (4) Benjamin Hull (b) (4)	31 Mar 2021 22:45:50

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:18:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:05
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:36:32
User entered empty.	(b) (4) Benjamin Hull (b) (4) (b) (4)	31 Mar 2021 22:45:50

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:18:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:05
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:36:32
User entered empty.	(b) (4) Benjamin Hull (b) (4) (b) (4)	31 Mar 2021 22:45:50

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:18:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:05
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:36:32
User entered empty.	(b) (4) Benjamin Hull (b) (4) (b) (4)	31 Mar 2021 22:45:50

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:18:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:05
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:36:32
User entered empty.	(b) (4) Benjamin Hull (b) (4) (b) (4)	31 Mar 2021 22:45:50

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:18:10

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '19 Dec 2020'	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 18:05:52

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:18:10

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 18:05:52

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:18:10

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 11:25:55
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'Covid19 event reported in Adverse events' (Site from System).	Nancy Tang (b) (4)	02 Feb 2021 18:06:18
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	02 Feb 2021 18:05:52
User entered 'Yes (Y)'	Nancy Tang (b) (4)	02 Feb 2021 18:05:52

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Folder: Covid-19 Assessment 19 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:18:10

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:18
User closed query 'Per CDM: A diagnostic test has been completed; however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 12:49:50
Query 'Per CDM: A diagnostic test has been completed; however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' answered with 'Illness visit was not completed by our study team. No Illness visit data available.' (Site from DM).	Nancy Tang (b) (4)	14 Apr 2021 17:04:36
User opened query 'Per CDM: A diagnostic test has been completed; however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 17:45:30
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 19-DEC-2020 is recorded under Covid-19 Assessment visit in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession, tracking number and shipped date else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 08:08:12
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 19-DEC-2020 is recorded under Covid-19 Assessment visit in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession, tracking number and shipped date else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'Accession Number: 1F60N9S' (Site from DM).	Benjamin Hull (b) (4) (b) (4)	02 Mar 2021 19:32:44

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Folder: Covid-19 Assessment 19 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:18:10

[Date of Test](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 19-DEC-2020 is recorded under Covid-19 Assessment visit in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession, tracking number and shipped date else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	16 Feb 2021 07:19:45
	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '19 Dec 2020'	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 18:05:52

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Folder: Covid-19 Assessment 19 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:18:10

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 18:05:52

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Folder: Covid-19 Assessment 19 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:18:10

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 18:05:52

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Folder: Covid-19 Assessment 19 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:18:10

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 18:05:52

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Folder: Covid-19 Assessment 19 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:18:10

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Subject reports Covid19 Nasopharyngeal swab test performed at Ensenada, Mexico hospital.'	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 18:05:52

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:18:10

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)'	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 18:05:52

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Folder: Covid-19 Assessment 19 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:18:10

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:18
User entered 'I'	System	02 Feb 2021 18:05:52

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Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:18:10

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)'	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:18:10

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:18:10

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:18:10

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:18:10

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)'	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:18:10

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:18:10

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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Folder: Covid-19 Assessment 19 Dec 2020

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Generated On: 10 Jun 2021 09:18:10

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:18:10

Did the subject have Oxygen Saturation of $\text{SpO}_2 \leq 93\%$ on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)'	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:18:10

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:18:10

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:18:10

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:18:10

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)'	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:18:10

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:18:10

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:18:10

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)'	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:18:10

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:18:10

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Feb 2021 21:34:11
User entered 'No (N)' reason for change: Data Entry Error	Nancy Tang (b) (4)	02 Feb 2021 21:34:11
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Feb 2021 21:34:04
User entered empty.	Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:18:10

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:18:10

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)'	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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Folder: Covid-19 Assessment 19 Dec 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:18:10

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:18:10

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)'	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:18:10

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:18:10

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:18:10

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)'	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:18:10

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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Folder: Covid-19 Assessment 19 Dec 2020

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Generated On: 10 Jun 2021 09:18:10

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:18:10

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)'	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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Folder: Covid-19 Assessment 19 Dec 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)'	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)'	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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Folder: Covid-19 Assessment 19 Dec 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:18:10

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)'	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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Folder: Covid-19 Assessment 19 Dec 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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Form: Covid-19 Severity Assessment

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)'	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

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Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:18:10

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:18:10

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)'	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:18:10

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:18:10

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)'	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:18:10

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:18:10

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:18:10

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:18:10

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:18:10

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '19 Dec 2020'	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:18:10

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '01 Jan 2021'	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 21:34:04

US3642333

Folder: Covid-19 Assessment 19 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:18:10

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:16:37
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	(b) (4) Nancy Tang (b) (4)	02 Feb 2021 18:06:35

US3642333

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:18:10

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:44:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)' reason for change: New Information	(b) (4) Nancy Tang (b) (4)	04 Jan 2021 04:10:08
User entered 'No (N)'	Son Do (b) (4)	23 Oct 2020 14:58:44

US3642333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:10

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	09 Apr 2021 00:03:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:39
User entered 'USA-US109-2021-mRNA-1273-P301000001'	System	04 Jan 2021 15:52:35
User entered 'New'	(b) (4), (b) (6)	04 Jan 2021 15:52:35

US3642333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:10

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	09 Apr 2021 00:03:18
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	04 Jan 2021 04:16:43
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Jan 2021 04:16:43
	(b) (4)	
Data point term sent to Coder	System	04 Jan 2021 04:16:13
User entered 'Covid19'	Nancy Tang (b) (4)	04 Jan 2021 04:15:19

US3642333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	09 Apr 2021 00:03:18
	(b) (4)	
User entered 'Yes (Y)'	Nancy Tang (b) (4)	04 Jan 2021 04:15:19

US3642333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	09 Apr 2021 00:03:18
	(b) (4)	
User entered 'No (N)'	Nancy Tang (b) (4)	04 Jan 2021 04:15:19

US3642333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	09 Apr 2021 00:03:18
User entered 'Yes (Y)'	(b) (4) Nancy Tang (b) (4)	04 Jan 2021 04:15:19

US3642333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	09 Apr 2021 00:03:18
	(b) (4)	
User entered '19 Dec 2020'	Nancy Tang (b) (4)	04 Jan 2021 04:15:19

US3642333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:10

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	09 Apr 2021 00:03:18
	(b) (4)	
User entered empty.	Nancy Tang (b) (4)	04 Jan 2021 04:15:19

US3642333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 04:15:19

US3642333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	09 Apr 2021 00:03:18
User closed query 'Per MM, please provide the end date. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 10:13:08
Query 'Per MM, please provide the end date. ' answered with 'Ongoing date updated per query request.' (Site from DM).	Nancy Tang (b) (4)	06 Apr 2021 20:01:12
User entered 'No (N)' reason for change: Data Entry Error	Nancy Tang (b) (4)	06 Apr 2021 20:00:57
User opened query 'Per MM, please provide the end date. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 17:35:44
User entered 'Yes (Y)'	Nancy Tang (b) (4)	04 Jan 2021 04:15:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	09 Apr 2021 00:03:18
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:19:53
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Subject reports negative Covid19 test on 04Feb2021 and recovered.' (Site from Safety).	Nancy Tang (b) (4)	06 Apr 2021 20:01:37
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	06 Apr 2021 20:00:57
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	06 Apr 2021 20:00:57
User entered '04 Feb 2021' reason for change: Per Query Resolution	Nancy Tang (b) (4)	06 Apr 2021 20:00:57
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	06 Apr 2021 19:59:17
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)	12 Jan 2021 15:09:45
User entered empty.	Nancy Tang (b) (4)	04 Jan 2021 04:15:19

US3642333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:10

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	09 Apr 2021 00:03:18
User entered empty.	(b) (4) Nancy Tang (b) (4)	04 Jan 2021 04:15:19

US3642333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 04:15:19

US3642333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:10

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	09 Apr 2021 00:03:18
User entered 'Grade 4 (Grade 4)'	(b) (4) Nancy Tang (b) (4)	04 Jan 2021 04:15:19

US3642333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	09 Apr 2021 00:03:18
User entered 'Yes (Y)'	(b) (4) Nancy Tang (b) (4)	04 Jan 2021 04:15:19

US3642333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:10

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	09 Apr 2021 00:03:18
	(b) (4)	
User entered '0'	Nancy Tang (b) (4)	04 Jan 2021 04:15:19

US3642333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:10

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	09 Apr 2021 00:03:18
	(b) (4)	
User entered '0'	Nancy Tang (b) (4)	04 Jan 2021 04:15:19

US3642333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	09 Apr 2021 00:03:18
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) (4), (b) (6)	03 Feb 2021 06:17:41
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 'Hospital admission date entered per query request' (Site from System).	Nancy Tang (b) (4)	02 Feb 2021 18:09:38
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	04 Jan 2021 04:15:19
User entered '1'	Nancy Tang (b) (4)	04 Jan 2021 04:15:19

US3642333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	09 Apr 2021 00:03:18
	(b) (4)	
User entered '19 Dec 2020'	Nancy Tang (b) (4)	04 Jan 2021 04:15:19

US3642333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:10

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	09 Apr 2021 00:03:18
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:19:59
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Subject received care out of country in Mexico and is unable to provide hospital discharge summary. Please close query.' (Site from Safety).	Nancy Tang (b) (4)	06 Apr 2021 19:58:33
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 18:09:59
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'Updated per subject's report of discharge date 01Jan2021.' (Site from Safety).	Nancy Tang (b) (4)	02 Feb 2021 21:36:43
User entered '01 Jan 2021' reason for change: Data Entry Error	Nancy Tang (b) (4)	02 Feb 2021 21:36:17
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 15:09:25
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 15:08:46
User entered empty.	Nancy Tang (b) (4)	04 Jan 2021 04:15:19

US3642333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	09 Apr 2021 00:03:18
	(b) (4)	
User entered 'Yes (Y)'	Nancy Tang (b) (4)	04 Jan 2021 04:15:19

US3642333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	09 Apr 2021 00:03:18
User closed query 'Admitted to ICU? is Yes, however System Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	(b) (4)	02 Feb 2021 21:37:21
Query 'Admitted to ICU? is Yes, however Number of System Days in ICU is missing. Please review and reconcile.' answered by data change (Site from System).		02 Feb 2021 21:37:21
User entered '14' reason for change: New Information	Nancy Tang (b) (4)	02 Feb 2021 21:37:21
User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	04 Jan 2021 04:15:19
User entered empty.	Nancy Tang (b) (4)	04 Jan 2021 04:15:19

US3642333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	09 Apr 2021 00:03:18
	(b) (4)	
User entered '0'	Nancy Tang (b) (4)	04 Jan 2021 04:15:19

US3642333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	09 Apr 2021 00:03:18
	(b) (4)	
User entered '0'	Nancy Tang (b) (4)	04 Jan 2021 04:15:19

US3642333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:10

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	09 Apr 2021 00:03:18
	(b) (4)	
User entered '0'	Nancy Tang (b) (4)	04 Jan 2021 04:15:19

US3642333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	09 Apr 2021 00:03:18
User entered 'Not Related (NOT RELATED)'	(b) (4) Nancy Tang (b) (4)	04 Jan 2021 04:15:19

US3642333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	09 Apr 2021 00:03:18
User entered 'Not Related (NOT RELATED)'	(b) (4) Nancy Tang (b) (4)	04 Jan 2021 04:15:19

US3642333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:10

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	09 Apr 2021 00:03:18
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Nancy Tang (b) (4)	04 Jan 2021 04:15:19

US3642333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:10

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	09 Apr 2021 00:03:18
	(b) (4)	
User entered '0'	Nancy Tang (b) (4)	04 Jan 2021 04:15:19

US3642333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	09 Apr 2021 00:03:18
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:20:06
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Subject received treatment out of country in Mexico and was unable to provide concomitant medications and treatment given information.' (Site from Safety).	Nancy Tang (b) (4)	06 Apr 2021 20:02:15
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)	12 Jan 2021 15:10:59
User entered 'I'	Nancy Tang (b) (4)	04 Jan 2021 04:15:19

US3642333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	09 Apr 2021 00:03:18
	(b) (4)	
User entered '0'	Nancy Tang (b) (4)	04 Jan 2021 04:15:19

US3642333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:10

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	09 Apr 2021 00:03:18
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:21:50
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Subject recovered from Covid19.' (Site from Safety).	Nancy Tang (b) (4)	06 Apr 2021 20:02:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Nancy Tang (b) (4)	06 Apr 2021 19:59:17
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 15:10:13
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Nancy Tang (b) (4)	04 Jan 2021 04:15:19

US3642333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	09 Apr 2021 00:03:18
	(b) (4)	
User entered empty.	Nancy Tang (b) (4)	04 Jan 2021 04:15:19

US3642333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:10

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	09 Apr 2021 00:03:18
User entered 'SUBJECT REPORTS THAT HE WAS HOSPITALIZED IN THE ICU AT ENSENADA, MEXICO FOR COVID19. HE BEGAN TO FEEL COVID19 SYMPTOMS ON 19DEC2020 BUT DID NOT CALL US SINCE HE WAS OUT OF COUNTRY. HE LATER WAS HOSPITALIZED IN CRITICAL CONDITION AND HAS RECOVERED SINCE THEN.' reason for change: Data Entry Error	Nancy Tang (b) (4)	06 Apr 2021 20:03:11
User closed query 'PV Query: Please confirm the Country in which the event occurred, per the narrative the subject was hospitalized in Mexico, is this where the event occurred?' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 18:10:30
User closed query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment.' (Site from Safety).		03 Feb 2021 18:10:18
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).		03 Feb 2021 18:10:08
Query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment.' answered with 'updated per query request from Subject's report' (Site from Safety).	Nancy Tang (b) (4)	02 Feb 2021 21:39:09
Query 'PV Query: Please confirm the Country in which the event occurred, per the narrative the subject was hospitalized in Mexico, is this where the event occurred?' answered with 'Yes, Adverse event occurred in Ensenada, Mexico per subject.' (Site from Safety).	Nancy Tang (b) (4)	02 Feb 2021 18:11:32
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'Per subject, Covid19 Nasopharyngeal swab pcr test was performed on 19Dec2020.' (Site from Safety).	Nancy Tang (b) (4)	02 Feb 2021 18:10:50

US3642333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:10

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm the Country in which the event occurred, per the narrative the subject was hospitalized in Mexico, is this where the event occurred?' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 15:11:32
User opened query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' (Site from Safety).		12 Jan 2021 15:11:17
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).		12 Jan 2021 15:10:30
User entered 'Subject reports that he is currently hospitalized in the ICU at Ensenada, Mexico for Covid19. He began to feel Covid19 symptoms on 19Dec2020 but did not call us since he was out of country. He later was hospitalized in critical condition and is now improving but still remains in the ICU.'	Nancy Tang (b) (4)	04 Jan 2021 04:15:19

US3642333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:10

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Jan 2021 04:15:19

US3642333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:10

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Jan 2021 04:15:19

US3642333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:10

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Jan 2021 04:15:19

US3642333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:18:10

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:44:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	Son Do (b) (4)	23 Oct 2020 14:57:43

US3642333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	10 Nov 2020 23:52:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 23:52:42
Data point term sent to Coder Coding entries removed.	System Megan Loughran (b) (4)	10 Nov 2020 23:52:05 10 Nov 2020 23:51:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 14:59:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 14:59:31
Data point term sent to Coder User entered 'metformin'	System Son Do (b) (4)	23 Oct 2020 14:58:39 23 Oct 2020 14:58:38

US3642333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)'	(b) (4) Son Do (b) (4)	23 Oct 2020 14:58:38

US3642333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
	(b) (4)	
User entered 'DIABETES type ii' reason for change:	Megan Loughran (b) (4)	10 Nov 2020 23:51:27
Data Entry Error	(b) (4)	
User entered 'diabetes'	Son Do (b) (4)	23 Oct 2020 14:58:38

US3642333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '1000'	(b) (4) Son Do (b) (4)	23 Oct 2020 14:58:38

US3642333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'mg (mg)'	(b) (4) Son Do (b) (4)	23 Oct 2020 14:58:38

US3642333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Son Do (b) (4)	23 Oct 2020 14:58:38

US3642333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'twice daily (BID)'	(b) (4) Son Do (b) (4)	23 Oct 2020 14:58:38

US3642333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Son Do (b) (4)	23 Oct 2020 14:58:38

US3642333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Oral (ORAL)'	(b) (4) Son Do (b) (4)	23 Oct 2020 14:58:38

US3642333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Son Do (b) (4)	23 Oct 2020 14:58:38

US3642333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:10

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

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'UN May 2000'	(b) (4) Son Do (b) (4)	23 Oct 2020 14:58:38

US3642333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '0'	(b) (4) Son Do (b) (4)	23 Oct 2020 14:58:38

US3642333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	23 Oct 2020 14:58:38

US3642333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered empty.	(b) (4) Son Do (b) (4)	23 Oct 2020 14:58:38

US3642333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)'	(b) (4) Son Do (b) (4)	23 Oct 2020 14:58:38

US3642333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Oct 2020 14:58:38

US3642333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 14:58:38

US3642333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 14:58:38

US3642333

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:18:10

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered 'No (N)'	(b) (4) Son Do (b) (4)	23 Oct 2020 14:57:37

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'USA-US109-2021-MRNA-1273-P301000001'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

Serious

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'Yes (Y)'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'No (N)'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'No (N)'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'Yes (Y)'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'No (N)'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'No (N)'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'No (N)'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'Stephen'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'Spector'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 18:12:45
User entered 'US'	System	04 Jan 2021 15:53:04

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	07 Apr 2021 16:22:24
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
	(b) (4)	
User entered '2'	System	03 Feb 2021 18:12:38
User entered '1'	System	04 Jan 2021 15:53:04

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'USA-US109-2021-MRNA-1273-P301000001'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

Serious

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'Yes (Y)'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'No (N)'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'No (N)'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'Yes (Y)'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'No (N)'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'No (N)'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'No (N)'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'Stephen'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'Spector'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 18:12:45
User entered 'US'	System	04 Jan 2021 15:53:04

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	07 Apr 2021 16:22:24
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
	(b) (4)	
User entered '2'	System	03 Feb 2021 18:12:38
User entered '1'	System	04 Jan 2021 15:53:04

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:18:10

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '04/Jan/2021 10:53'	(b) (4) System	04 Jan 2021 15:53:04

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:18:10

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.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 18:12:45
User entered 'I'		04 Jan 2021 15:53:04

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'USA-US109-2021-MRNA-1273-P301000001'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

Serious

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'Yes (Y)'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'No (N)'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'No (N)'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'Yes (Y)'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'No (N)'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'No (N)'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'No (N)'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'Stephen'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'Spector'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 18:12:45
User entered 'US'	System	04 Jan 2021 15:53:04

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	07 Apr 2021 16:22:24
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
	(b) (4)	
User entered '2'	System	03 Feb 2021 18:12:38
User entered '1'	System	04 Jan 2021 15:53:04

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:18:10

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
User entered '03/Feb/2021 13:12'	(b) (4) System	03 Feb 2021 18:12:38

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:18:10

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.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 18:12:45
User entered 'I'		03 Feb 2021 18:12:38

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'USA-US109-2021-MRNA-1273-P301000001'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

Serious

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'Yes (Y)'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'No (N)'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'No (N)'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'Yes (Y)'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'No (N)'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'No (N)'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'No (N)'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'Stephen'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:52:54
User entered 'Spector'	System	04 Jan 2021 15:52:35

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 18:12:45
User entered 'US'	System	04 Jan 2021 15:53:04

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	07 Apr 2021 16:22:24
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 19:38:00
	(b) (4)	
User entered '2'	System	03 Feb 2021 18:12:38
User entered '1'	System	04 Jan 2021 15:53:04

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:18:10

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	09 Apr 2021 00:03:18
User entered '07/Apr/2021 12:22'	(b) (4) System	07 Apr 2021 16:22:24

US3642333

Folder: SAE USA-US109-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:18:10

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.	Stephen Spector (b) (4)	09 Apr 2021 00:03:18
User entered 'I'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:22:24