

US3672333 (Prod: Coastal Carolina Research Center)

Generated By: KC Joubran

Generated On: 26 Nov 2020 11:11:23

All time stamps listed in this document are displayed in GMT

US3672333

Form: Participant Creation

Generated On: 26 Nov 2020 11:11:23

[Participant ID](#)

US3672333

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

US3672333

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:11:23

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	26 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

US3672333

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:11:23

Date of Birth (MMM yyyy)	(b) (6) 2000
Age	19
Age Units	YEARS
Age (Derived)	19
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
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

US3672333

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:11:23

Date of Informed Consent (<i>dd MMM yyyy</i>)	26 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☒
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

US3672333

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:11:23

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3672333

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:11:23

Were any significant conditions reported?

Yes ☒

No ☐

US3672333

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:11:23

Condition	ADHD ATTENTION DEFICIT HYPERACTIVITY DISORDER
Start date (dd MMM yyyy)	UN UNK 2006
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	
Stop Year (derived)	

US3672333

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	26 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	16:33 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 16:33
Height (<i>xxx.x</i>)	161.5 cm
Weight (<i>xxx.x</i>)	77.9 kg
BMI (<i>xxx.x</i>)	29.86706 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
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)	

US3672333

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:11:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 AUG 2020

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

US3672333

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:11:23

Date of assessment (*dd MMM yyyy*) 26 AUG 2020

Is the participant of childbearing potential? Yes ☒ No ☐

If No, what is the reason? Surgically sterile ☐
Post-menopausal ☐
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (*dd MMM yyyy*) _____

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) _____

Date of last menstruation unknown False

US3672333

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:11:23

Was the pregnancy test performed?	Yes ☒
	No ☐
Date of test (<i>dd MMM yyyy</i>)	26 AUG 2020
Test performed	Urine ☒
	Serum ☐
Result	Positive ☐
	Negative ☒
Was FSH sample collected?	Yes ☐
	No ☒
Collection date	
Collection time	
Collection date and time (derived)	

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:23

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
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:23

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	True
Specify	RESIDENT IN A COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION.

US3672333

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:11:23

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	26 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

US3672333

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:11:23

What was the date of randomization? (dd MMM yyyy) 26 AUG 2020

What was the participant's randomization number? 108965

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 ☐

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:11:23

Height	ND - Not Done
Weight	ND - Not Done

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:23

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	26 AUG 2020
Time of assessment (00:00-23:59)	16:33 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 16:33
Temperature (xxx.x)	98.3 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:23

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	26 AUG 2020
Time of assessment (00:00-23:59)	17:38 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 17:38
Temperature (xxx.x)	98.9 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3672333

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:11:23

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.

US3672333

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:11:23

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed _____ Urine ☐

Serum ☐

Result _____ Positive ☐

Negative ☐

Was FSH sample collected? Yes ☐

No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

US3672333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:11:23

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)	26 AUG 2020
What was the treatment time? (00:00-23:59)	17:06 (24 HR)
Treatment Date and Time (derived)	26 AUG 2020 17:06
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

US3672333

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:11:23

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 AUG 2020

Collection time (00:00-23:59)

16:52 (24 HR)

Collection date and time (derived)

26 AUG 2020 16:52

US3672333

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:11:23

Collection date (<i>dd MMM yyyy</i>)			26 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:23	26 AUG 2020 16:23
Nasopharyngeal Swab 2	No		

US3672333

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:11:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:11:23

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

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 17:42

PC Open Date & Time

26 AUG 2020 17:26

PC Close Date & Time

26 AUG 2020 19:56

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 21:37

PC Open Date & Time

26 AUG 2020 20:51

PC Close Date & Time

27 AUG 2020 11:59

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:11:23

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 12:00

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 13:07

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:11:23

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 13:48

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 12:01

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 12:01

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:11:23

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

96.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 19:15

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 17:43

PC Open Date & Time

26 AUG 2020 17:26

PC Close Date & Time

26 AUG 2020 19:56

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:11:23

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

26 AUG 2020 21:37

PC Open Date & Time

26 AUG 2020 20:51

PC Close Date & Time

27 AUG 2020 11:59

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:11:23

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

27 AUG 2020 12:01

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:11:23

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

28 AUG 2020 13:08

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:11:23

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

29 AUG 2020 13:48

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:11:23

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

30 AUG 2020 12:01

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:11:23

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

31 AUG 2020 12:02

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:11:23

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

01 SEP 2020 19:16

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:11:23

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 ☐

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:11:23

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 17:44
PC Open Date & Time	26 AUG 2020 17:26
PC Close Date & Time	26 AUG 2020 19:56

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:11:23

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 ☐

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:11:23

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 21:38
PC Open Date & Time	26 AUG 2020 20:51
PC Close Date & Time	27 AUG 2020 11:59

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:11:23

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 ☒

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:11:23

Yes ☐	
PC Time stamp	27 AUG 2020 12:01
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:11:23

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 ☒

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:11:23

Yes ☐	
PC Time stamp	28 AUG 2020 13:08
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:11:23

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 ☒

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:11:23

Yes ☐	
PC Time stamp	29 AUG 2020 13:48
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:11:23

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 ☒

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:11:23

Yes ☐	
PC Time stamp	30 AUG 2020 12:01
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:11:23

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 ☒

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:11:23

Yes ☐	
PC Time stamp	31 AUG 2020 12:02
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:11:23

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 ☒

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:11:23

Yes ☐	
PC Time stamp	01 SEP 2020 19:16
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3672333

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

HEADACHE

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 ☐

PC Time Stamp 03 SEP 2020 08:40

PC Open Date & Time 02 SEP 2020 12:00

PC Close Date & Time 03 SEP 2020 11:59

US3672333

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	03 SEP 2020 08:40
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3672333

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:23

Was Contact Attempted?

Yes ☒

No ☐

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

02 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672333

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672333

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672333

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672333

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:23

Was Contact Attempted?

Yes ☒

No ☐

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

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672333

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672333

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:11:23

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	23 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:23

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	23 SEP 2020
Time of assessment (00:00-23:59)	15:15 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 15:15
Temperature (xxx.x)	98.4 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:23

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

US3672333

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:11:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 SEP 2020

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

US3672333

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:11:23

Was the pregnancy test performed?	Yes ☒
	No ☐
Date of test (<i>dd MMM yyyy</i>)	23 SEP 2020
Test performed	Urine ☒
	Serum ☐
Result	Positive ☐
	Negative ☒
Was FSH sample collected?	Yes ☐
	No ☒
Collection date	
Collection time	
Collection date and time (derived)	

US3672333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:11:23

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

NO SWAB RESULT FOUND FROM DAY 1

What was the study treatment? _____

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

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

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3672333

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:11:23

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	23 SEP 2020
Collection time (<i>00:00-23:59</i>)	15:30 (24 HR)
Collection date and time (derived)	23 SEP 2020 15:30

US3672333

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:11:23

Collection date (dd MMM yyyy)			23 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:30	23 SEP 2020 15:30
Nasopharyngeal Swab 2	No		

US3672333

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672333

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:23

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

US3672333

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672333

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672333

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672333

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672333

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672333

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:11:23

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	21 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3672333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	21 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	16:16 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 16:16
Temperature (<i>xxx.x</i>)	98.2 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	80 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	68 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3672333

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:11:23

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.

US3672333

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:11:23

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	21 OCT 2020
Collection time (<i>00:00-23:59</i>)	16:32 (24 HR)
Collection date and time (derived)	21 OCT 2020 16:32

US3672333

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 OCT 2020 00:01:49
Patient Cloud Open Date & Time	26 OCT 2020 00:01
Patient Cloud Close Date & Time	30 OCT 2020 23:59

US3672333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 NOV 2020 00:01:30

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3672333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 12:01:06

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2020 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2020 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

06 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2020 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

13 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2020 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 NOV 2020 00:01:51

Patient Cloud Open Date & Time

20 NOV 2020 00:01

Patient Cloud Close Date & Time

24 NOV 2020 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

27 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2020 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

DAY 103

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

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

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

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

04 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2020 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2020 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

18 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2020 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

25 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2020 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

12 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

[Patient Cloud Close Date & Time](#)

23 FEB 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

12 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

02 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

DAY 229

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

09 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

10 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

12 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

14 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

21 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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 ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3672333

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672333

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672333

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:23

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

US3672333

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:23

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:11:23

Date of Contact	30 SEP 2020
Time of Contact	10:55
Date and Time of Contact (derived)	30 SEP 2020 10:55
Type of Contact	Clinic Visit - Scheduled ☒
	Clinical Visit - Unscheduled ☐
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☒
	No ☐

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:11:23

Symptom Day

Day 1	☒
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:11:23

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	30 SEP 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.5 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	305 of 1499	

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:11:23

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:11:23

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:11:23

Symptom Day

Day 1	☐
Day 2	☒
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:11:23

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	1 OCT 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	309 of 1499	

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:11:23

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:11:23

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:11:23

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☒
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:11:23

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	2 OCT 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.9 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	313 of 1499	

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:11:23

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:11:23

	Severe	☒
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:11:23

Date of Visit	30 SEP 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	30 SEP 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	_____
CLIA Certified?	Yes ☐ No ☐
COVID-19 Positive (CSA Programming Field Only)	0

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:11:23

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

US3672333

Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 11:11:23

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	30 SEP 2020
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3672333

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:11:23

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	30 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD1

US3672333

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	30 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:55 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 10:55
Height (<i>xxx.x</i>)	160.0 cm
Weight (<i>xxx.x</i>)	78.7 kg
Temperature (<i>xxx.x</i>)	98.5 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	68 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3672333

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:11:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 SEP 2020

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

US3672333

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 11:11:23

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

30 SEP 2020

US3672333

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:11:23

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 _____

US3672333

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

Were vital signs assessed?	Yes ☐
	No ☐
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 ☐
	Axillary ☐
	Other ☐
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)	

US3672333

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:11:23

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.

US3672333

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 11:11:23

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection _____

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 11:11:23

Visit Date	30 SEP 2020
Please check all assessments that apply for this visit	
Physical Exam	False
Vital Signs	True
Immunogenicity Assessment	True
Pregnancy Test	True

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	30 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	15:15 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 15:15
Temperature (<i>xxx.x</i>)	98.4 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	78 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	89 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:11:23

Was the pregnancy test performed?	Yes ☒
	No ☐
Date of test (<i>dd MMM yyyy</i>)	30 SEP 2020
Test performed	Urine ☒
	Serum ☐
Result	Positive ☐
	Negative ☒
Was FSH sample collected?	Yes ☐
	No ☒
Collection date	
Collection time	
Collection date and time (derived)	

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:11:23

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	30 SEP 2020
Collection time (<i>00:00-23:59</i>)	15:35 (24 HR)
Collection date and time (derived)	30 SEP 2020 15:35

US3672333

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:11:23

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:23

AEID	
Adverse event	LYMPHADENOPATHY R UNDERARM
Was this a medically-attended AE?	Yes ☐ No ☒
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	7 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

v6.020 DTW (1102) 332 of 1499

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:23

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

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:23

AEID	
Adverse event	UPPER RESPIRATORY INFECTION (URI)
Was this a medically-attended AE?	Yes ☐ No ☒
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	24 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	30 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

v6.020 DTW (1102)

334 of 1499

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:23

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

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:11:23

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

Yes ☒

No ☐

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

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:23

Name of Medication	NEXPLANON
Prophylaxis	Yes ☐ No ☒
Indication	CONTRACEPTION
Dose per administration	68
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	EVERY 3 YEARS Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:23

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☒
If route of administration is Other, specify	SUBDERMAL	
Start date (dd MMM yyyy)	26 NOV 2018	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:23

Name of Medication	INFLUENZA VACCINE
Prophylaxis	Yes ☒ No ☐
Indication	INFLUENZA PROPHYLAXIS
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	INJECTION
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 ☐ Intramuscular ☒

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:23

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		9 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		9 NOV 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3672333

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:11:23

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3672333

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:11:23

Date of dosing discontinuation (dd MMM yyyy)

23 SEP 2020

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

AE#1 AND DOSING
DISCONTINUED DUE TO DAY 1
SWAB NEVER FOUND.

US3672333

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:11:23

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 ☐

Audit

US3672333 (Prod: Coastal Carolina Research Center)

US3672333

Form: Participant Creation

Generated On: 26 Nov 2020 11:11:23

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3672333'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	26 Aug 2020 20:29:36

US3672333

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:11:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 21:01:54

US3672333

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '26 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	26 Aug 2020 20:29:37

US3672333

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	26 Aug 2020 21:01:54

US3672333

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:11:23

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	26 Aug 2020 21:01:54

US3672333

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:11:23

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 2000'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	26 Aug 2020 20:29:38

US3672333

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:11:23

[Age](#)

Audit	User	Time (GMT)
User entered '19'	(b) (4), (b) (6)	28 Aug 2020 17:58:42

US3672333

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:11:23

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	28 Aug 2020 17:58:42

US3672333

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:11:23

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '19'	System	26 Aug 2020 21:02:06

US3672333

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:11:23

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	(b) (4), (b) (6)	28 Aug 2020 17:58:42

US3672333

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:11:23

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	28 Aug 2020 17:58:42

US3672333

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:11:23

White

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	28 Aug 2020 17:58:42

US3672333

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:11:23

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 17:58:42

US3672333

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:11:23

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 17:58:42

US3672333

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:11:23

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 17:58:42

US3672333

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:11:23

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 17:58:42

US3672333

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:11:23

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 17:58:42

US3672333

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:11:23

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 17:58:42

US3672333

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:11:23

Unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 17:58:42

US3672333

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:11:23

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 17:58:42

US3672333

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '26 Aug 2020'	(b) (4), (b) (6)	26 Aug 2020 21:02:06

US3672333

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	26 Aug 2020 21:02:06

US3672333

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '2020'	System	26 Aug 2020 21:02:06

US3672333

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:11:23

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	26 Aug 2020 21:02:06

US3672333

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 21:02:06

US3672333

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 21:02:06

US3672333

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:11:23

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 21:02:06

US3672333

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:11:23

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 21:02:06

US3672333

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:11:23

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	26 Aug 2020 20:29:37

US3672333

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:11:23

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 21:02:10

US3672333

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 21:02:10

US3672333

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:11:23

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 17:58:51

US3672333

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:11:23

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: Attention deficit hyperactivity disorder - version MedDRA\23.0.	Coder Import (b) (4)	31 Oct 2020 20:56:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	31 Oct 2020 20:56:25
User closed query 'Per MM: please expand the abbreviation.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 18:53:54
Data point term sent to Coder	System	21 Oct 2020 13:26:23
Query 'Per MM: please expand the abbreviation.' answered with 'Expanded per query.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 13:25:51
Coding entries removed.	(b) (4), (b) (6)	21 Oct 2020 13:25:42
User entered 'ADHD Attention Deficit Hyperactivity Disorder' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 13:25:42
User opened query 'Per MM: please expand the abbreviation.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 20:00:36
User coded data point as SOC: Psychiatric disorders, HLGT: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: ADHD - version MedDRA\23.0.	Coder Import (b) (4)	28 Aug 2020 18:00:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	28 Aug 2020 18:00:43
Data point term sent to Coder	System	28 Aug 2020 17:59:35
User entered 'ADHD'	(b) (4), (b) (6)	28 Aug 2020 17:59:04

US3672333

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered 'un UNK 2006'	(b) (4), (b) (6)	28 Aug 2020 17:59:04

US3672333

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:11:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 17:59:04

US3672333

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:11:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 17:59:04

US3672333

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 17:59:04

US3672333

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:11:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 17:59:04

US3672333

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered 'Jan 2006'	System	28 Aug 2020 17:59:04

US3672333

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '2006'	System	28 Aug 2020 17:59:04

US3672333

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 17:59:04

US3672333

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 17:59:04

US3672333

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 17:59:31

US3672333

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 17:59:31

US3672333

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '16:33'	(b) (4), (b) (6)	28 Aug 2020 17:59:31

US3672333

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '26 Aug 2020 16:33'	System	28 Aug 2020 17:59:31

US3672333

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '161.5' cm	(b) (4), (b) (6)	28 Aug 2020 17:59:31
DataPoint set to visible.	System	26 Aug 2020 21:02:10

US3672333

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '77.9' kg	(b) (4), (b) (6)	28 Aug 2020 17:59:31
DataPoint set to visible.	System	26 Aug 2020 21:02:10

US3672333

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '29.86706'	System	28 Aug 2020 17:59:31
DataPoint set to visible.	System	26 Aug 2020 21:02:10

US3672333

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	28 Aug 2020 17:59:31
DataPoint set to visible.	System	26 Aug 2020 21:02:10

US3672333

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	28 Aug 2020 17:59:31

US3672333

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 17:59:31

US3672333

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 17:59:31

US3672333

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	28 Aug 2020 17:59:31

US3672333

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Aug 2020 17:59:31

US3672333

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	28 Aug 2020 17:59:31

US3672333

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Aug 2020 17:59:31

US3672333

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	28 Aug 2020 17:59:31

US3672333

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Aug 2020 17:59:31

US3672333

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	28 Aug 2020 17:59:31

US3672333

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Aug 2020 17:59:31

US3672333

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:11:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 18:37:25

US3672333

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:11:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 18:37:25

US3672333

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:11:23

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 18:37:33

US3672333

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:11:23

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 18:37:33

US3672333

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:11:23

[If No, what is the reason?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:37:33

US3672333

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:11:23

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:37:33

US3672333

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:11:23

If Surgically sterile, date of surgery (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:37:33

US3672333

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:11:23

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 18:37:33

US3672333

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:11:23

If Post-menopausal, date of last menstruation (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:37:33

US3672333

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:11:23

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 18:37:33

US3672333

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:11:23

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 18:37:44

US3672333

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:11:23

[Date of test \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 18:37:44

US3672333

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:11:23

[Test performed](#)

Audit	User	Time (GMT)
User entered 'Urine (URINE)'	(b) (4), (b) (6)	28 Aug 2020 18:37:44

US3672333

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:11:23

[Result](#)

Audit	User	Time (GMT)
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	28 Aug 2020 18:37:44

US3672333

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:11:23

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:37:44

US3672333

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:11:23

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:37:44

US3672333

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:11:23

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:37:44

US3672333

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 18:37:44

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:23

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:23

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:23

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:23

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:23

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:23

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:23

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:23

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:23

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:23

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:23

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:23

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:23

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:23

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:23

[Other](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:23

[Specify](#)

Audit	User	Time (GMT)
User entered 'Resident in a community with ongoing person to person transmission.'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:11:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 18:38:38

US3672333

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '26 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 18:38:38

US3672333

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	28 Aug 2020 18:38:38

US3672333

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:11:23

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	28 Aug 2020 18:38:38

US3672333

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '26 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	26 Aug 2020 20:49:28

US3672333

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '108965'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	26 Aug 2020 20:49:28

US3672333

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	26 Aug 2020 20:49:28

US3672333

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:11:23

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:38:50

US3672333

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:11:23

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:38:50

US3672333

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:38:50

US3672333

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:11:23

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:38:50

US3672333

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:11:23

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:38:50

US3672333

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:47:23
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:08:35

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:11:23

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:11:23

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:11:23

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:11:23

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:23

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '16:33'	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '26 Aug 2020 16:33'	System	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:23

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.3' F	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:23

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:23

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '78'	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:23

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '13'	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '107'	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '66'	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:23

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:11:23

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:11:23

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:23

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '17:38'	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '26 Aug 2020 17:38'	System	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:23

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.9' F	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:23

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:23

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '91'	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:23

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '18'	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '103'	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '66'	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:23

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:11:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:40:30

US3672333

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:11:23

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:40:30

US3672333

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:11:23

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please note if screening and Visit date is on the same day, kindly change the Pregnancy test performed on Visit 1 to "NO". Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 08:11:14
Query 'Per CDM: Please note if screening and Visit date is on the same day, kindly change the Pregnancy test performed on Visit 1 to "NO". Thank you.'	(b) (4), (b) (6)	28 Sep 2020 21:50:30
answered with 'updated' (Site from DM).		
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 21:50:28
User opened query 'Per CDM: Please note if screening and Visit date is on the same day, kindly change the Pregnancy test performed on Visit 1 to "NO". Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 06:17:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 18:40:40

US3672333

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:11:23

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 21:50:28
User entered '26 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 18:40:40

US3672333

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:11:23

[Test performed](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 21:50:28
User entered 'Urine (URINE)'	(b) (4), (b) (6)	28 Aug 2020 18:40:40

US3672333

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:11:23

[Result](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 21:50:28
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	28 Aug 2020 18:40:40

US3672333

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:11:23

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:40:40

US3672333

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:11:23

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:40:40

US3672333

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:11:23

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:40:40

US3672333

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 18:40:40

US3672333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:11:23

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 21:40:25

US3672333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:11:23

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 21:40:25

US3672333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 21:40:25

US3672333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:11:23

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	26 Aug 2020 21:40:25

US3672333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:11:23

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	(b) (4), (b) (6)	26 Aug 2020 21:40:25

US3672333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '17:06'	(b) (4), (b) (6)	26 Aug 2020 21:40:25

US3672333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '26 Aug 2020 17:06'	System	26 Aug 2020 21:40:25

US3672333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered 'Right Arm (RIGHT ARM)'	(b) (4), (b) (6)	26 Aug 2020 21:40:25

US3672333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	26 Aug 2020 21:40:25

US3672333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:11:23

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	26 Aug 2020 21:40:25

US3672333

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:11:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 18:40:58

US3672333

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:11:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 18:40:58

US3672333

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '16:52'	(b) (4), (b) (6)	28 Aug 2020 18:40:58

US3672333

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '26 Aug 2020 16:52'	System	28 Aug 2020 18:40:58

US3672333

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:11:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 18:41:10

US3672333

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:11:23

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	28 Aug 2020 18:41:10

US3672333

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:11:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 18:41:10

US3672333

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:11:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '16:23'	(b) (4), (b) (6)	28 Aug 2020 18:41:10

US3672333

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '26 Aug 2020 16:23'	System	28 Aug 2020 18:41:10

US3672333

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:11:23

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	28 Aug 2020 18:41:10

US3672333

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:11:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:41:10

US3672333

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:11:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:41:10

US3672333

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 18:41:10

US3672333

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 18:41:15

US3672333

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:11:23

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 18:41:15

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:11:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T17:42:49', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '7a278dfd-7ee6-4853-8d81-99e21f5d5564'	System	26 Aug 2020 21:43:06
User entered 'Yes (Y)'	System	26 Aug 2020 21:43:06

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:11:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T17:42:54', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '7a278dfd-7ee6-4853-8d81-99e21f5d5564'	System	26 Aug 2020 21:43:06
User entered '98.9'	System	26 Aug 2020 21:43:06

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T17:42:57', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '7a278dfd-7ee6-4853-8d81-99e21f5d5564'	System	26 Aug 2020 21:43:06
User entered 'No (N)'	System	26 Aug 2020 21:43:06

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:11:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T17:42:59', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '7a278dfd-7ee6-4853-8d81-99e21f5d5564'	System	26 Aug 2020 21:43:06
User entered '26 Aug 2020 17:42'	System	26 Aug 2020 21:43:06

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:11:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 17:26'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:11:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 19:56'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:11:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T21:37:27', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '69fcd28b-2c1c-4311-bd43-45f0a3d0afb5'	System	27 Aug 2020 01:37:38
User entered 'Yes (Y)'	System	27 Aug 2020 01:37:38

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:11:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T21:37:31', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '69fcd28b-2c1c-4311-bd43-45f0a3d0afb5'	System	27 Aug 2020 01:37:38
User entered '98.3'	System	27 Aug 2020 01:37:38

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T21:37:34', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '69fcd28b-2c1c-4311-bd43-45f0a3d0afb5'	System	27 Aug 2020 01:37:38
User entered 'No (N)'	System	27 Aug 2020 01:37:38

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:11:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T21:37:37', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '69fcd28b-2c1c-4311-bd43-45f0a3d0afb5'	System	27 Aug 2020 01:37:38
User entered '26 Aug 2020 21:37'	System	27 Aug 2020 01:37:38

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:11:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 20:51'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:11:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 2'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:11:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-27T12:00:38', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'd092be52-780c-469d-8ef7-681d7283b797'	System	27 Aug 2020 16:00:54
User entered 'Yes (Y)'	System	27 Aug 2020 16:00:54

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:11:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-27T12:00:44', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'd092be52-780c-469d-8ef7-681d7283b797'	System	27 Aug 2020 16:00:54
User entered '97.9'	System	27 Aug 2020 16:00:54

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-27T12:00:46', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'd092be52-780c-469d-8ef7-681d7283b797'	System	27 Aug 2020 16:00:54
User entered 'No (N)'	System	27 Aug 2020 16:00:54

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:11:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-27T12:00:48', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'd092be52-780c-469d-8ef7-681d7283b797'	System	27 Aug 2020 16:00:54
User entered '27 Aug 2020 12:00'	System	27 Aug 2020 16:00:54

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:11:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:11:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 3'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:11:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-28T13:07:48', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '0141c041-cb40-4b63-aa55-0b4a7dd28679'	System	28 Aug 2020 17:08:00
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:00

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:11:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-28T13:07:52', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '0141c041-cb40-4b63-aa55-0b4a7dd28679'	System	28 Aug 2020 17:08:00
User entered '98.3'	System	28 Aug 2020 17:08:00

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-28T13:07:54', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '0141c041-cb40-4b63-aa55-0b4a7dd28679'	System	28 Aug 2020 17:08:00
User entered 'No (N)'	System	28 Aug 2020 17:08:00

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:11:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-28T13:07:56', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '0141c041-cb40-4b63-aa55-0b4a7dd28679'	System	28 Aug 2020 17:08:00
User entered '28 Aug 2020 13:07'	System	28 Aug 2020 17:08:00

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:11:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:11:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 4'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:11:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-29T13:48:06', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'ad306163-e5f9-40e1-af8a-8ed7be4c01e7'	System	29 Aug 2020 18:48:19
User entered 'Yes (Y)'	System	29 Aug 2020 18:48:19

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:11:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-29T13:48:13', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'ad306163-e5f9-40e1-af8a-8ed7be4c01e7'	System	29 Aug 2020 18:48:19
User entered '96.8'	System	29 Aug 2020 18:48:19

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-29T13:48:15', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'ad306163-e5f9-40e1-af8a-8ed7be4c01e7'	System	29 Aug 2020 18:48:19
User entered 'No (N)'	System	29 Aug 2020 18:48:19

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:11:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-29T13:48:16', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'ad306163-e5f9-40e1-af8a-8ed7be4c01e7'	System	29 Aug 2020 18:48:19
User entered '29 Aug 2020 13:48'	System	29 Aug 2020 18:48:19

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:11:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:11:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 5'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:11:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-30T12:00:44', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '15e54e1a-c372-4fc9-8fb4-39f8f8a7d68a' User entered 'Yes (Y)'	System	30 Aug 2020 17:01:09

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:11:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-30T12:00:50', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '15e54e1a-c372-4fc9-8fb4-39f8f8a7d68a' User entered '98.1'	System	30 Aug 2020 17:01:09

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-30T12:00:56', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '15e54e1a-c372-4fc9-8fb4-39f8f8a7d68a'	System	30 Aug 2020 17:01:09
User entered 'No (N)'	System	30 Aug 2020 17:01:09

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:11:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-30T12:01:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '15e54e1a-c372-4fc9-8fb4-39f8f8a7d68a' User entered '30 Aug 2020 12:01'	System	30 Aug 2020 17:01:09

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:11:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:11:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 6'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:11:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-31T12:01:51', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'de3b2333-6911-4621-942b-90801609ddd2'	System	31 Aug 2020 17:14:21
User entered 'Yes (Y)'	System	31 Aug 2020 17:14:21

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:11:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-31T12:01:54', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'de3b2333-6911-4621-942b-90801609ddd2'	System	31 Aug 2020 17:14:21
User entered '98.6'	System	31 Aug 2020 17:14:21

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-31T12:01:56', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'de3b2333-6911-4621-942b-90801609ddd2'	System	31 Aug 2020 17:14:21
User entered 'No (N)'	System	31 Aug 2020 17:14:21

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:11:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-31T12:01:58', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'de3b2333-6911-4621-942b-90801609ddd2'	System	31 Aug 2020 17:14:21
User entered '31 Aug 2020 12:01'	System	31 Aug 2020 17:14:21

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:11:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:11:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:11:23

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 7'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:11:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-01T19:15:46', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '2c78903a-dac0-4f2f-b13f-64e565517bc6'	System	01 Sep 2020 23:15:54
User entered 'Yes (Y)'	System	01 Sep 2020 23:15:54

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:11:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-01T19:15:49', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '2c78903a-dac0-4f2f-b13f-64e565517bc6'	System	01 Sep 2020 23:15:54
User entered '96.2'	System	01 Sep 2020 23:15:54

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-01T19:15:51', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '2c78903a-dac0-4f2f-b13f-64e565517bc6'	System	01 Sep 2020 23:15:54
User entered 'No (N)'	System	01 Sep 2020 23:15:54

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:11:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-01T19:15:52', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '2c78903a-dac0-4f2f-b13f-64e565517bc6'	System	01 Sep 2020 23:15:54
User entered '01 Sep 2020 19:15'	System	01 Sep 2020 23:15:54

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:11:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:11:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:11:23

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T17:43:04', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '16109b97-da36-4350-a11f-98caea2c7b8f'	System	26 Aug 2020 21:43:54
User entered 'None (1)'	System	26 Aug 2020 21:43:54

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T17:43:06', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '16109b97-da36-4350-a11f-98caea2c7b8f'	System	26 Aug 2020 21:43:54
User entered 'No (N)'	System	26 Aug 2020 21:43:54

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T17:43:12', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '16109b97-da36-4350-a11f-98caea2c7b8f'	System	26 Aug 2020 21:43:54
User entered 'No (N)'	System	26 Aug 2020 21:43:54

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:11:23

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T17:43:15', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '16109b97-da36-4350-a11f-98caea2c7b8f'	System	26 Aug 2020 21:43:54
User entered 'None (1)'	System	26 Aug 2020 21:43:54

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:11:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T17:43:52', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '16109b97-da36-4350-a11f-98caea2c7b8f'	System	26 Aug 2020 21:43:54
User entered '26 Aug 2020 17:43'	System	26 Aug 2020 21:43:54

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:11:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 17:26'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:11:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 19:56'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:11:23

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T21:37:40', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '28ed5e38-070f-4b12-8165-5f553b06dde3'	System	27 Aug 2020 01:37:56
User entered 'None (1)'	System	27 Aug 2020 01:37:56

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:11:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T21:37:42', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '28ed5e38-070f-4b12-8165-5f553b06dde3'	System	27 Aug 2020 01:37:56
User entered 'No (N)'	System	27 Aug 2020 01:37:56

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T21:37:43', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '28ed5e38-070f-4b12-8165-5f553b06dde3'	System	27 Aug 2020 01:37:56
User entered 'No (N)'	System	27 Aug 2020 01:37:56

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:11:23

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T21:37:52', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '28ed5e38-070f-4b12-8165-5f553b06dde3'	System	27 Aug 2020 01:37:56
User entered 'None (1)'	System	27 Aug 2020 01:37:56

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:11:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T21:37:55', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '28ed5e38-070f-4b12-8165-5f553b06dde3'	System	27 Aug 2020 01:37:56
User entered '26 Aug 2020 21:37'	System	27 Aug 2020 01:37:56

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:11:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 20:51'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:11:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 2'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:11:23

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-27T12:00:55', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'cfcfd9c3-3c2b-467b-a0a1-b1f3f9de4144'	System	27 Aug 2020 16:01:21
User entered 'None (1)'	System	27 Aug 2020 16:01:21

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:11:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-27T12:00:57', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'cfcfd9c3-3c2b-467b-a0a1-b1f3f9de4144'	System	27 Aug 2020 16:01:21
User entered 'No (N)'	System	27 Aug 2020 16:01:21

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-27T12:01:04', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'cfcfd9c3-3c2b-467b-a0a1-b1f3f9de4144'	System	27 Aug 2020 16:01:21
User entered 'No (N)'	System	27 Aug 2020 16:01:21

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:11:23

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-27T12:01:07', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'cfcfd9c3-3c2b-467b-a0a1-b1f3f9de4144'	System	27 Aug 2020 16:01:21
User entered 'None (1)'	System	27 Aug 2020 16:01:21

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:11:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-27T12:01:09', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'cfcfd9c3-3c2b-467b-a0a1-b1f3f9de4144'	System	27 Aug 2020 16:01:21
User entered '27 Aug 2020 12:01'	System	27 Aug 2020 16:01:21

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:11:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:11:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 3'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:11:23

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-28T13:07:59', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '4e0f4cec-1990-425b-ae08-a47255b48652'	System	28 Aug 2020 17:08:11
User entered 'None (1)'	System	28 Aug 2020 17:08:11

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:11:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-28T13:08:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '4e0f4cec-1990-425b-ae08-a47255b48652'	System	28 Aug 2020 17:08:11
User entered 'No (N)'	System	28 Aug 2020 17:08:11

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-28T13:08:01', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '4e0f4cec-1990-425b-ae08-a47255b48652'	System	28 Aug 2020 17:08:11
User entered 'No (N)'	System	28 Aug 2020 17:08:11

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:11:23

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-28T13:08:03', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '4e0f4cec-1990-425b-ae08-a47255b48652'	System	28 Aug 2020 17:08:11
User entered 'None (1)'	System	28 Aug 2020 17:08:11

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:11:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-28T13:08:06', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '4e0f4cec-1990-425b-ae08-a47255b48652'	System	28 Aug 2020 17:08:11
User entered '28 Aug 2020 13:08'	System	28 Aug 2020 17:08:11

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:11:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:11:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 4'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:11:23

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-29T13:48:19', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'eb35ac98-7eb2-4022-81d9-7275a67cb061'	System	29 Aug 2020 18:48:28
User entered 'None (1)'	System	29 Aug 2020 18:48:28

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:11:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-29T13:48:21', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'eb35ac98-7eb2-4022-81d9-7275a67cb061'	System	29 Aug 2020 18:48:28
User entered 'No (N)'	System	29 Aug 2020 18:48:28

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-29T13:48:23', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'eb35ac98-7eb2-4022-81d9-7275a67cb061'	System	29 Aug 2020 18:48:28
User entered 'No (N)'	System	29 Aug 2020 18:48:28

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:11:23

[Please record - UNDERARM GLAND SWELLING OR TENDERNESS.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-29T13:48:24', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'eb35ac98-7eb2-4022-81d9-7275a67cb061'	System	29 Aug 2020 18:48:28
User entered 'None (1)'	System	29 Aug 2020 18:48:28

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:11:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-29T13:48:26', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'eb35ac98-7eb2-4022-81d9-7275a67cb061'	System	29 Aug 2020 18:48:28
User entered '29 Aug 2020 13:48'	System	29 Aug 2020 18:48:28

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:11:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:11:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 5'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:11:23

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-30T12:01:05', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'b0130488-f0eb-4709-8823-e12fa8bdbd3a'	System	30 Aug 2020 17:01:22
User entered 'None (1)'	System	30 Aug 2020 17:01:22

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:11:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-30T12:01:13', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'b0130488-f0eb-4709-8823-e12fa8bdbd3a'	System	30 Aug 2020 17:01:22
User entered 'No (N)'	System	30 Aug 2020 17:01:22

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-30T12:01:14', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'b0130488-f0eb-4709-8823-e12fa8bdbd3a'	System	30 Aug 2020 17:01:22
User entered 'No (N)'	System	30 Aug 2020 17:01:22

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:11:23

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-30T12:01:15', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'b0130488-f0eb-4709-8823-e12fa8bdbd3a'	System	30 Aug 2020 17:01:22
User entered 'None (1)'	System	30 Aug 2020 17:01:22

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:11:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-30T12:01:17', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'b0130488-f0eb-4709-8823-e12fa8bdbd3a' User entered '30 Aug 2020 12:01'	System	30 Aug 2020 17:01:22
	System	30 Aug 2020 17:01:22

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:11:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:11:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 6'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:11:23

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-31T12:02:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '67ef119c-2734-4d2f-9aea-80bfc946d201'	System	31 Aug 2020 17:14:24
User entered 'None (1)'	System	31 Aug 2020 17:14:24

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:11:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-31T12:02:02', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '67ef119c-2734-4d2f-9aea-80bfc946d201'	System	31 Aug 2020 17:14:24
User entered 'No (N)'	System	31 Aug 2020 17:14:24

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-31T12:02:03', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '67ef119c-2734-4d2f-9aea-80bfc946d201'	System	31 Aug 2020 17:14:24
User entered 'No (N)'	System	31 Aug 2020 17:14:24

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:11:23

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-31T12:02:04', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '67ef119c-2734-4d2f-9aea-80bfc946d201'	System	31 Aug 2020 17:14:24
User entered 'None (1)'	System	31 Aug 2020 17:14:24

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:11:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-31T12:02:06', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '67ef119c-2734-4d2f-9aea-80bfc946d201'	System	31 Aug 2020 17:14:24
User entered '31 Aug 2020 12:02'	System	31 Aug 2020 17:14:24

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:11:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:11:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 7'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:11:23

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-01T19:15:54', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '47de99dc-dddb-45de-9715-7b15e78829a3'	System	01 Sep 2020 23:16:01
User entered 'None (1)'	System	01 Sep 2020 23:16:01

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:11:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-01T19:15:56', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '47de99dc-dddb-45de-9715-7b15e78829a3'	System	01 Sep 2020 23:16:01
User entered 'No (N)'	System	01 Sep 2020 23:16:01

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-01T19:15:57', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '47de99dc-dddb-45de-9715-7b15e78829a3'	System	01 Sep 2020 23:16:01
User entered 'No (N)'	System	01 Sep 2020 23:16:01

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:11:23

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-01T19:15:58', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '47de99dc-dddb-45de-9715-7b15e78829a3'	System	01 Sep 2020 23:16:01
User entered 'None (1)'	System	01 Sep 2020 23:16:01

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:11:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-01T19:16:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '47de99dc-dddb-45de-9715-7b15e78829a3'	System	01 Sep 2020 23:16:01
User entered '01 Sep 2020 19:16'	System	01 Sep 2020 23:16:01

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:11:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:11:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:11:23

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T17:43:59', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '5563ee68-2ec3-461c-ada0-c35acf56463a' User entered 'None (0)'	System	26 Aug 2020 21:44:20
	System	26 Aug 2020 21:44:20

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:11:23

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T17:44:01', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '5563ee68-2ec3-461c-ada0-c35acf56463a' User entered 'None (0)'	System	26 Aug 2020 21:44:20
	System	26 Aug 2020 21:44:20

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:11:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T17:44:03', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '5563ee68-2ec3-461c-ada0-c35acf56463a' User entered 'None (0)'	System	26 Aug 2020 21:44:20
	System	26 Aug 2020 21:44:20

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:11:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T17:44:06', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '5563ee68-2ec3-461c-ada0-c35acf56463a' User entered 'None (0)'	System	26 Aug 2020 21:44:20
	System	26 Aug 2020 21:44:20

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:11:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T17:44:08', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '5563ee68-2ec3-461c-ada0-c35acf56463a' User entered 'None (0)'	System	26 Aug 2020 21:44:20
	System	26 Aug 2020 21:44:20

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:11:23

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T17:44:10', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '5563ee68-2ec3-461c-ada0-c35acf56463a' User entered 'None (0)'	System	26 Aug 2020 21:44:20
	System	26 Aug 2020 21:44:20

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T17:44:16', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '5563ee68-2ec3-461c-ada0-c35acf56463a' User entered 'No (N)'	System	26 Aug 2020 21:44:20

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:11:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T17:44:17', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '5563ee68-2ec3-461c-ada0-c35acf56463a' User entered '26 Aug 2020 17:44'	System	26 Aug 2020 21:44:20
	System	26 Aug 2020 21:44:20

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:11:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 17:26'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:11:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 19:56'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:11:23

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T21:37:57', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'a2455866-501c-420b-a337-09c1a3aca32b'	System	27 Aug 2020 01:38:15
User entered 'None (0)'	System	27 Aug 2020 01:38:15

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:11:23

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T21:37:59', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'a2455866-501c-420b-a337-09c1a3aca32b'	System	27 Aug 2020 01:38:15
User entered 'None (0)'	System	27 Aug 2020 01:38:15

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:11:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T21:38:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'a2455866-501c-420b-a337-09c1a3aca32b' User entered 'None (0)'	System	27 Aug 2020 01:38:15
	System	27 Aug 2020 01:38:15

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:11:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T21:38:01', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'a2455866-501c-420b-a337-09c1a3aca32b'	System	27 Aug 2020 01:38:15
User entered 'None (0)'	System	27 Aug 2020 01:38:15

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:11:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T21:38:02', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'a2455866-501c-420b-a337-09c1a3aca32b' User entered 'None (0)'	System	27 Aug 2020 01:38:15
	System	27 Aug 2020 01:38:15

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:11:23

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T21:38:04', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'a2455866-501c-420b-a337-09c1a3aca32b'	System	27 Aug 2020 01:38:15
User entered 'None (0)'	System	27 Aug 2020 01:38:15

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T21:38:08', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'a2455866-501c-420b-a337-09c1a3aca32b'	System	27 Aug 2020 01:38:15
User entered 'No (N)'	System	27 Aug 2020 01:38:15

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:11:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T21:38:10', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'a2455866-501c-420b-a337-09c1a3aca32b' User entered '26 Aug 2020 21:38'	System	27 Aug 2020 01:38:15

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:11:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 20:51'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:11:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 2'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:11:23

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-27T12:01:12', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'e153d150-70dd-4a28-9610-67b8cfc5ee5c'	System	27 Aug 2020 16:01:42
User entered 'None (0)'	System	27 Aug 2020 16:01:42

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:11:23

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-27T12:01:13', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'e153d150-70dd-4a28-9610-67b8cfc5ee5c'	System	27 Aug 2020 16:01:42
User entered 'None (0)'	System	27 Aug 2020 16:01:42

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:11:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-27T12:01:14', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'e153d150-70dd-4a28-9610-67b8cfc5ee5c'	System	27 Aug 2020 16:01:42
User entered 'None (0)'	System	27 Aug 2020 16:01:42

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:11:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-27T12:01:18', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'e153d150-70dd-4a28-9610-67b8cfc5ee5c'	System	27 Aug 2020 16:01:42
User entered 'No interference with activity (1)'	System	27 Aug 2020 16:01:42

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:11:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-27T12:01:20', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'e153d150-70dd-4a28-9610-67b8cfc5ee5c'	System	27 Aug 2020 16:01:42
User entered 'None (0)'	System	27 Aug 2020 16:01:42

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:11:23

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-27T12:01:22', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'e153d150-70dd-4a28-9610-67b8cfc5ee5c'	System	27 Aug 2020 16:01:42
User entered 'No interference with activity (1)'	System	27 Aug 2020 16:01:42

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-27T12:01:25', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'e153d150-70dd-4a28-9610-67b8cfc5ee5c'	System	27 Aug 2020 16:01:42
User entered 'No (N)'	System	27 Aug 2020 16:01:42

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:11:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-27T12:01:27', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'e153d150-70dd-4a28-9610-67b8cfc5ee5c'	System	27 Aug 2020 16:01:42
User entered '27 Aug 2020 12:01'	System	27 Aug 2020 16:01:42

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:11:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:11:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 3'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:11:23

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-28T13:08:10', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '4b6caea7-da22-42f9-bfab-b449874c1313'	System	28 Aug 2020 17:08:37
User entered 'None (0)'	System	28 Aug 2020 17:08:37

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:11:23

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-28T13:08:12', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '4b6caea7-da22-42f9-bfab-b449874c1313'	System	28 Aug 2020 17:08:37
User entered 'None (0)'	System	28 Aug 2020 17:08:37

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:11:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-28T13:08:13', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '4b6caea7-da22-42f9-bfab-b449874c1313'	System	28 Aug 2020 17:08:37
User entered 'None (0)'	System	28 Aug 2020 17:08:37

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:11:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-28T13:08:15', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '4b6caea7-da22-42f9-bfab-b449874c1313'	System	28 Aug 2020 17:08:37
User entered 'None (0)'	System	28 Aug 2020 17:08:37

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:11:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-28T13:08:26', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '4b6caea7-da22-42f9-bfab-b449874c1313'	System	28 Aug 2020 17:08:37
User entered 'None (0)'	System	28 Aug 2020 17:08:37

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:11:23

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-28T13:08:29', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '4b6caea7-da22-42f9-bfab-b449874c1313'	System	28 Aug 2020 17:08:37
User entered 'None (0)'	System	28 Aug 2020 17:08:37

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-28T13:08:31', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '4b6caea7-da22-42f9-bfab-b449874c1313'	System	28 Aug 2020 17:08:37
User entered 'No (N)'	System	28 Aug 2020 17:08:37

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:11:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-28T13:08:33', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '4b6caea7-da22-42f9-bfab-b449874c1313'	System	28 Aug 2020 17:08:37
User entered '28 Aug 2020 13:08'	System	28 Aug 2020 17:08:37

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:11:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:11:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 4'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:11:23

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-29T13:48:28', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '606dfa27-4a00-422a-911e-d940ef350be3'	System	29 Aug 2020 18:48:48
User entered 'None (0)'	System	29 Aug 2020 18:48:48

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:11:23

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-29T13:48:30', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '606dfa27-4a00-422a-911e-d940ef350be3'	System	29 Aug 2020 18:48:48
User entered 'None (0)'	System	29 Aug 2020 18:48:48

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:11:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-29T13:48:31', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '606dfa27-4a00-422a-911e-d940ef350be3'	System	29 Aug 2020 18:48:48
User entered 'None (0)'	System	29 Aug 2020 18:48:48

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:11:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-29T13:48:33', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '606dfa27-4a00-422a-911e-d940ef350be3'	System	29 Aug 2020 18:48:48
User entered 'None (0)'	System	29 Aug 2020 18:48:48

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:11:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-29T13:48:34', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '606dfa27-4a00-422a-911e-d940ef350be3'	System	29 Aug 2020 18:48:48
User entered 'None (0)'	System	29 Aug 2020 18:48:48

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:11:23

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-29T13:48:35', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '606dfa27-4a00-422a-911e-d940ef350be3'	System	29 Aug 2020 18:48:48
User entered 'None (0)'	System	29 Aug 2020 18:48:48

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-29T13:48:37', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '606dfa27-4a00-422a-911e-d940ef350be3'	System	29 Aug 2020 18:48:48
User entered 'No (N)'	System	29 Aug 2020 18:48:48

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:11:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-29T13:48:45', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '606dfa27-4a00-422a-911e-d940ef350be3'	System	29 Aug 2020 18:48:48
User entered '29 Aug 2020 13:48'	System	29 Aug 2020 18:48:48

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:11:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:11:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 5'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:11:23

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-30T12:01:19', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'c310b51e-83fa-4e5d-817a-850db23826a1'	System	30 Aug 2020 17:01:48
User entered 'None (0)'	System	30 Aug 2020 17:01:48

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:11:23

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-30T12:01:21', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'c310b51e-83fa-4e5d-817a-850db23826a1'	System	30 Aug 2020 17:01:48
User entered 'None (0)'	System	30 Aug 2020 17:01:48

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:11:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-30T12:01:36', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'c310b51e-83fa-4e5d-817a-850db23826a1'	System	30 Aug 2020 17:01:48
User entered 'None (0)'	System	30 Aug 2020 17:01:48

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:11:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-30T12:01:38', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'c310b51e-83fa-4e5d-817a-850db23826a1' User entered 'None (0)'	System	30 Aug 2020 17:01:48
	System	30 Aug 2020 17:01:48

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:11:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-30T12:01:39', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'c310b51e-83fa-4e5d-817a-850db23826a1'	System	30 Aug 2020 17:01:48
User entered 'None (0)'	System	30 Aug 2020 17:01:48

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:11:23

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-30T12:01:40', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'c310b51e-83fa-4e5d-817a-850db23826a1'	System	30 Aug 2020 17:01:48
User entered 'None (0)'	System	30 Aug 2020 17:01:48

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-30T12:01:42', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'c310b51e-83fa-4e5d-817a-850db23826a1'	System	30 Aug 2020 17:01:48
User entered 'No (N)'	System	30 Aug 2020 17:01:48

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:11:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-30T12:01:45', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'c310b51e-83fa-4e5d-817a-850db23826a1' User entered '30 Aug 2020 12:01'	System	30 Aug 2020 17:01:48
	System	30 Aug 2020 17:01:48

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:11:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:11:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 6'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:11:23

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-31T12:02:08', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '19791bf6-9b61-4e11-b153-cfe50fbff926'	System	31 Aug 2020 17:14:34
User entered 'None (0)'	System	31 Aug 2020 17:14:34

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:11:23

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-31T12:02:09', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '19791bf6-9b61-4e11-b153-cfe50fbff926'	System	31 Aug 2020 17:14:34
User entered 'None (0)'	System	31 Aug 2020 17:14:34

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:11:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-31T12:02:10', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '19791bf6-9b61-4e11-b153-cfe50fbff926'	System	31 Aug 2020 17:14:34
User entered 'None (0)'	System	31 Aug 2020 17:14:34

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:11:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-31T12:02:12', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '19791bf6-9b61-4e11-b153-cfe50fbff926'	System	31 Aug 2020 17:14:34
User entered 'None (0)'	System	31 Aug 2020 17:14:34

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:11:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-31T12:02:13', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '19791bf6-9b61-4e11-b153-cfe50fbff926'	System	31 Aug 2020 17:14:34
User entered 'None (0)'	System	31 Aug 2020 17:14:34

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:11:23

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-31T12:02:14', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '19791bf6-9b61-4e11-b153-cfe50fbff926'	System	31 Aug 2020 17:14:34
User entered 'None (0)'	System	31 Aug 2020 17:14:34

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-31T12:02:15', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '19791bf6-9b61-4e11-b153-cfe50fbff926'	System	31 Aug 2020 17:14:34
User entered 'No (N)'	System	31 Aug 2020 17:14:34

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:11:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-31T12:02:20', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '19791bf6-9b61-4e11-b153-cfe50fbff926'	System	31 Aug 2020 17:14:34
User entered '31 Aug 2020 12:02'	System	31 Aug 2020 17:14:34

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:11:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:11:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 7'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:11:23

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-01T19:16:07', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '63740731-4183-4c5a-b180-3ffd5a4e69f8'	System	01 Sep 2020 23:16:20
User entered 'No interference with activity (1)'	System	01 Sep 2020 23:16:20

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:11:23

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-01T19:16:08', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '63740731-4183-4c5a-b180-3ffd5a4e69f8'	System	01 Sep 2020 23:16:20
User entered 'None (0)'	System	01 Sep 2020 23:16:20

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:11:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-01T19:16:09', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '63740731-4183-4c5a-b180-3ffd5a4e69f8'	System	01 Sep 2020 23:16:20
User entered 'None (0)'	System	01 Sep 2020 23:16:20

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:11:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-01T19:16:10', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '63740731-4183-4c5a-b180-3ffd5a4e69f8'	System	01 Sep 2020 23:16:20
User entered 'None (0)'	System	01 Sep 2020 23:16:20

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:11:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-01T19:16:11', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '63740731-4183-4c5a-b180-3ffd5a4e69f8'	System	01 Sep 2020 23:16:20
User entered 'None (0)'	System	01 Sep 2020 23:16:20

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:11:23

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-01T19:16:13', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '63740731-4183-4c5a-b180-3ffd5a4e69f8'	System	01 Sep 2020 23:16:20
User entered 'None (0)'	System	01 Sep 2020 23:16:20

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-01T19:16:15', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '63740731-4183-4c5a-b180-3ffd5a4e69f8'	System	01 Sep 2020 23:16:20
User entered 'No (N)'	System	01 Sep 2020 23:16:20

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:11:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-01T19:16:16', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '63740731-4183-4c5a-b180-3ffd5a4e69f8'	System	01 Sep 2020 23:16:20
User entered '01 Sep 2020 19:16'	System	01 Sep 2020 23:16:20

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:11:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:11:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 23:16:20
User entered 'Day 8'	System	01 Sep 2020 23:16:20

US3672333

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 11:11:23

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-03T08:40:30', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '93393911-746c-4f7d-ab62-e3d766ad04e9'	System	03 Sep 2020 12:40:40
User entered 'None (0)'	System	03 Sep 2020 12:40:40

US3672333

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 11:11:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-03T08:40:35', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '93393911-746c-4f7d-ab62-e3d766ad04e9' User entered '03 Sep 2020 08:40'	System	03 Sep 2020 12:40:40
	System	03 Sep 2020 12:40:40

US3672333

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 11:11:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 23:16:20

US3672333

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 11:11:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 23:16:20

US3672333

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 23:16:20
User entered 'Day 8'	System	01 Sep 2020 23:16:20

US3672333

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-03T08:40:39', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '785461a1-2cb3-4c9d-b9a7-834f191a63a3'	System	03 Sep 2020 12:40:42
User entered 'No (N)'	System	03 Sep 2020 12:40:42

US3672333

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:11:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-03T08:40:41', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '785461a1-2cb3-4c9d-b9a7-834f191a63a3'	System	03 Sep 2020 12:40:42
User entered '03 Sep 2020 08:40'	System	03 Sep 2020 12:40:42

US3672333

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:11:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 23:16:20

US3672333

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:11:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 23:16:20

US3672333

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 13:37:12

US3672333

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:23

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 13:37:12

US3672333

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	03 Sep 2020 13:37:12

US3672333

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 13:37:12

US3672333

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 13:37:18

US3672333

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:23

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 13:37:18

US3672333

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Patty Howenstine (b) (4) (b) (4)	14 Sep 2020 17:38:19

US3672333

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:23

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '9 Sep 2020'	Patty Howenstine (b) (4) (b) (4)	14 Sep 2020 17:38:19

US3672333

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Patty Howenstine (b) (4)	14 Sep 2020 17:38:19

US3672333

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Patty Howenstine (b) (4) (b) (4)	14 Sep 2020 17:38:19

US3672333

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Patty Howenstine (b) (4) (b) (4)	14 Sep 2020 17:38:23

US3672333

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:23

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 17:38:23

US3672333

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Query 'Per CDM: Visit 2 Day 29 has not been completed in the database; but GCL has a record of Visit 2 Day 29 Immunogenicity Sample dated 23SEP2020. Please review and reconcile and, if appropriate, complete the Immunogenicity Assessment.' canceled (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 12:17:02
User opened query 'Per CDM: Visit 2 Day 29 has not been completed in the database; but GCL has a record of Visit 2 Day 29 Immunogenicity Sample dated 23SEP2020. Please review and reconcile and, if appropriate, complete the Immunogenicity Assessment.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 09:57:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 15:46:52

US3672333

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '16 Sep 2020'	(b) (4), (b) (6)	16 Sep 2020 15:46:52

US3672333

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Sep 2020 15:46:52

US3672333

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 15:46:52

US3672333

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User closed query 'Per CDM: Visit 2 Day 29 has not been completed in the database; but Visit 2 Day 29 Immunogenicity Sample is expected at GCL. Please review and reconcile and, if appropriate, complete the Immunogenicity Assessment at Visit 2 Day 29.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 10:13:45
Query 'Per CDM: Visit 2 Day 29 has not been completed in the database; but Visit 2 Day 29 Immunogenicity Sample is expected at GCL. Please review and reconcile and, if appropriate, complete the Immunogenicity Assessment at Visit 2 Day 29.' answered with 'Data has been entered.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 13:28:38
User opened query 'Per CDM: Visit 2 Day 29 has not been completed in the database; but Visit 2 Day 29 Immunogenicity Sample is expected at GCL. Please review and reconcile and, if appropriate, complete the Immunogenicity Assessment at Visit 2 Day 29.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 12:17:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 15:46:55

US3672333

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:23

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 15:46:55

US3672333

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:11:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Oct 2020 19:56:34

US3672333

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '23 Sep 2020'	(b) (4), (b) (6)	11 Oct 2020 19:56:34

US3672333

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Oct 2020 19:56:34

US3672333

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:11:23

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	11 Oct 2020 19:56:34

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:23

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:23

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '15:15'	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '23 Sep 2020 15:15'	System	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:23

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.4' F	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:23

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:23

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:23

Pulse (xxx)

Audit	User	Time (GMT)
User entered '78'	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:23

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '17'	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '137'	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '89'	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:23

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:23

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered empty.	System	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:23

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:23

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:23

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:23

Pulse (xxx)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:23

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:23

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:11:23

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Oct 2020 20:04:11

US3672333

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:11:23

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	(b) (4), (b) (6)	11 Oct 2020 20:04:11

US3672333

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:11:23

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Oct 2020 20:11:58

US3672333

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:11:23

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	(b) (4), (b) (6)	11 Oct 2020 20:11:58

US3672333

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:11:23

[Test performed](#)

Audit	User	Time (GMT)
User entered 'Urine (URINE)'	(b) (4), (b) (6)	11 Oct 2020 20:11:58

US3672333

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:11:23

[Result](#)

Audit	User	Time (GMT)
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	11 Oct 2020 20:11:58

US3672333

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:11:23

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Oct 2020 20:11:58

US3672333

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:11:23

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 20:11:58

US3672333

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:11:23

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 20:11:58

US3672333

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered empty.	System	11 Oct 2020 20:11:58

US3672333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:11:23

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Oct 2020 20:13:19

US3672333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:11:23

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	(b) (4), (b) (6)	11 Oct 2020 20:13:19

US3672333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered 'No swab result found from Day 1'	(b) (4), (b) (6)	11 Oct 2020 20:13:19

US3672333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:11:23

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Oct 2020 20:13:19

US3672333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:11:23

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 20:13:19

US3672333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 20:13:19

US3672333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered empty.	System	11 Oct 2020 20:13:19

US3672333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 20:13:19

US3672333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered empty.	System	11 Oct 2020 20:13:19

US3672333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:11:23

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Oct 2020 20:13:19

US3672333

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:11:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Oct 2020 20:12:51

US3672333

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:11:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	(b) (4), (b) (6)	11 Oct 2020 20:12:51

US3672333

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:11:23

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '15:30'	(b) (4), (b) (6)	11 Oct 2020 20:12:51

US3672333

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '23 Sep 2020 15:30'	System	11 Oct 2020 20:12:51

US3672333

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:11:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	(b) (4), (b) (6)	11 Oct 2020 20:13:38

US3672333

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:11:23

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	11 Oct 2020 20:13:38

US3672333

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:11:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Oct 2020 20:13:38

US3672333

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '15:30'	(b) (4), (b) (6)	11 Oct 2020 20:13:38

US3672333

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '23 Sep 2020 15:30'	System	11 Oct 2020 20:13:38

US3672333

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:11:23

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	11 Oct 2020 20:13:38

US3672333

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:11:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Oct 2020 20:13:38

US3672333

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:11:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 20:13:38

US3672333

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered empty.	System	11 Oct 2020 20:13:38

US3672333

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Oct 2020 20:13:41

US3672333

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:23

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Oct 2020 20:13:41

US3672333

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Oct 2020 20:13:51

US3672333

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 20:13:51

US3672333

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 20:13:51

US3672333

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 20:13:51

US3672333

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Oct 2020 20:13:55

US3672333

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:23

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Oct 2020 20:13:55

US3672333

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Oct 2020 20:14:02

US3672333

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '11 Oct 2020'	(b) (4), (b) (6)	11 Oct 2020 20:14:02

US3672333

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Oct 2020 20:14:02

US3672333

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 20:14:02

US3672333

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Oct 2020 20:14:05

US3672333

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:23

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Oct 2020 20:14:05

US3672333

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 15:04:28

US3672333

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '14 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 15:04:28

US3672333

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Oct 2020 15:04:28

US3672333

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 15:04:28

US3672333

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 15:04:42

US3672333

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:23

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 15:04:42

US3672333

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:11:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 20:35:58

US3672333

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '21 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 20:35:58

US3672333

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	21 Oct 2020 20:35:58

US3672333

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:11:23

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	21 Oct 2020 20:35:58

US3672333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 20:36:44

US3672333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 20:36:44

US3672333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '16:16'	(b) (4), (b) (6)	21 Oct 2020 20:36:44

US3672333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '21 Oct 2020 16:16'	System	21 Oct 2020 20:36:44

US3672333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.2' F	(b) (4), (b) (6)	21 Oct 2020 20:36:44

US3672333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	21 Oct 2020 20:36:44

US3672333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 20:36:44

US3672333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '80'	(b) (4), (b) (6)	21 Oct 2020 20:36:44

US3672333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Oct 2020 20:36:44

US3672333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	21 Oct 2020 20:36:44

US3672333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Oct 2020 20:36:44

US3672333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '109'	(b) (4), (b) (6)	21 Oct 2020 20:36:44

US3672333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Oct 2020 20:36:44

US3672333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '68'	(b) (4), (b) (6)	21 Oct 2020 20:36:44

US3672333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Oct 2020 20:36:44

US3672333

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:11:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 20:36:51

US3672333

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:11:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 20:36:51

US3672333

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:11:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 20:42:22

US3672333

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '21 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 20:42:22

US3672333

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '16:32'	(b) (4), (b) (6)	21 Oct 2020 20:42:22

US3672333

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '21 Oct 2020 16:32'	System	21 Oct 2020 20:42:22

US3672333

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 20:42:28

US3672333

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:23

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 20:42:28

US3672333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 64'	System	26 Aug 2020 21:40:25

US3672333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-10-26T00:01:30', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'a8962d61-2e8a-4bf5-8806-6570e1010118' User entered 'No (N)'	System	26 Oct 2020 04:01:55
	System	26 Oct 2020 04:01:55

US3672333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-10-26T00:01:33', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'a8962d61-2e8a-4bf5-8806-6570e1010118'	System	26 Oct 2020 04:01:55
User entered 'No (N)'	System	26 Oct 2020 04:01:55

US3672333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-10-26T00:01:49', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'a8962d61-2e8a-4bf5-8806-6570e1010118' User entered '26 Oct 2020 00:01:49'	System	26 Oct 2020 04:01:55
	System	26 Oct 2020 04:01:55

US3672333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 21:40:25
User entered '26 Oct 2020 00:01'	System	26 Aug 2020 21:40:25

US3672333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 21:40:25
User entered '30 Oct 2020 23:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 71'	System	26 Aug 2020 21:40:25

US3672333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-11-02T00:01:23', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'd0f65598-bef0-48b6-8651-c8c5c4b32818'	System	02 Nov 2020 05:01:33
User entered 'No (N)'	System	02 Nov 2020 05:01:33

US3672333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-11-02T00:01:27', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'd0f65598-bef0-48b6-8651-c8c5c4b32818'	System	02 Nov 2020 05:01:33
User entered 'No (N)'	System	02 Nov 2020 05:01:33

US3672333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-11-02T00:01:30', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'd0f65598-bef0-48b6-8651-c8c5c4b32818'	System	02 Nov 2020 05:01:33
User entered '02 Nov 2020 00:01:30'	System	02 Nov 2020 05:01:33

US3672333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 21:40:25
User entered '02 Nov 2020 00:01'	System	26 Aug 2020 21:40:25

US3672333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 21:40:25
User entered '06 Nov 2020 23:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 78'	System	26 Aug 2020 21:40:25

US3672333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-11-11T12:00:52', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '248e6b34-a91d-4423-a6c0-abeb60e196e3' User entered 'No (N)'	System	11 Nov 2020 17:01:32
	System	11 Nov 2020 17:01:32

US3672333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-11-11T12:00:55', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '248e6b34-a91d-4423-a6c0-abeb60e196e3'	System	11 Nov 2020 17:01:32
User entered 'No (N)'	System	11 Nov 2020 17:01:32

US3672333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-11-11T12:01:06', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '248e6b34-a91d-4423-a6c0-abeb60e196e3' User entered '11 Nov 2020 12:01:06'	System	11 Nov 2020 17:01:32
	System	11 Nov 2020 17:01:32

US3672333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 21:40:25
User entered '09 Nov 2020 00:01'	System	26 Aug 2020 21:40:25

US3672333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 21:40:25
User entered '13 Nov 2020 23:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '23 Oct 2020 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '27 Oct 2020 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '30 Oct 2020 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '03 Nov 2020 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '06 Nov 2020 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '10 Nov 2020 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '13 Nov 2020 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '17 Nov 2020 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-11-23T00:01:48', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '7656025c-3768-40f8-9e7e-dd877bafba01'	System	23 Nov 2020 05:01:56
User entered 'No (N)'	System	23 Nov 2020 05:01:56

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-11-23T00:01:49', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '7656025c-3768-40f8-9e7e-dd877bafba01'	System	23 Nov 2020 05:01:56
User entered 'No (N)'	System	23 Nov 2020 05:01:56

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-11-23T00:01:51', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '7656025c-3768-40f8-9e7e-dd877bafba01' User entered '23 Nov 2020 00:01:51'	System	23 Nov 2020 05:01:56
	System	23 Nov 2020 05:01:56

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '28 Oct 2022 00:01'	System	19 Nov 2020 18:34:00

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '01 Nov 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 20:31:28

US3672333

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:23

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '19 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 20:31:28

US3672333

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	19 Nov 2020 20:31:28

US3672333

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:31:28

US3672333

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 20:31:32

US3672333

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:23

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 20:31:32

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:11:23

[Date of Contact](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Re-query: Thank you for the response, however please confirm the correct date for Day 3 saliva sample collected. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 05:31:23
User closed query 'Per GCL Lab Reconciliation: Saliva: Re-query: Response noted, however please confirm the sample collection date as Sample dated 02OCT2020 is reported under Illness Visits in PPD Central lab, thank you.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 05:31:23
Query 'Per GCL Lab Reconciliation: Saliva: Re-query: Response noted, however please confirm the sample collection date as Sample dated 02OCT2020 is reported under Illness Visits in PPD Central lab, thank you.' answered with 'Date must be reconciled by PPD central lab, date is unable to be changed by site.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 20:24:15
User opened query 'Per GCL Lab Reconciliation: Saliva: Re-query: Response noted, however please confirm the sample collection date as Sample dated 02OCT2020 is reported under Illness Visits in PPD Central lab, thank you.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 05:47:43
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Saliva Collection form of the illness visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 05:47:43
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Saliva Collection form of the illness visit. Else clarify, thank you.' answered with 'subject performed a saliva swab at an outside facility.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 14:21:42

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:11:23

[Date of Contact](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Saliva Collection form of the illness visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 04:40:44
User entered '30 Sep 2020'	(b) (4), (b) (6)	13 Oct 2020 14:37:36

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:11:23

[Time of Contact](#)

Audit	User	Time (GMT)
User entered '10:55'	(b) (4), (b) (6)	13 Oct 2020 14:37:36

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:11:23

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 10:55'	System	13 Oct 2020 14:37:36

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:11:23

[Type of Contact](#)

Audit	User	Time (GMT)
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	(b) (4), (b) (6)	13 Oct 2020 14:37:36

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:11:23

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 14:37:36

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:11:23

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)'	(b) (4), (b) (6)	13 Oct 2020 14:38:33

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:11:23

[Date](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	(b) (4), (b) (6)	13 Oct 2020 14:38:33

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:11:23

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 14:38:33

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:11:23

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '100'	(b) (4), (b) (6)	13 Oct 2020 14:38:33

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:11:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	13 Oct 2020 14:38:33

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:11:23

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.5' F	(b) (4), (b) (6)	13 Oct 2020 14:38:33

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:11:23

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:38:33

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:11:23

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:38:33

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:11:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:38:33

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:11:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:38:33

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:11:23

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:38:33

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:11:23

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:38:33

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:11:23

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:38:33

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:11:23

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:38:33

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:11:23

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:38:33

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:11:23

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:38:33

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:11:23

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	13 Oct 2020 14:38:33

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:11:23

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:38:33

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:11:23

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:38:33

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:11:23

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:38:33

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:11:23

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:38:33

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:11:23

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:38:33

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:11:23

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	(b) (4), (b) (6)	13 Oct 2020 14:39:26

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:11:23

[Date](#)

Audit	User	Time (GMT)
User entered '1 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 14:39:26

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:11:23

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 14:39:26

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:11:23

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '100'	(b) (4), (b) (6)	13 Oct 2020 14:39:26

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:11:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	13 Oct 2020 14:39:26

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:11:23

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.6' F	(b) (4), (b) (6)	13 Oct 2020 14:39:26

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:11:23

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:39:26

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:11:23

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:39:26

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:11:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:39:26

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:11:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:39:26

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:11:23

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:39:26

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:11:23

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:39:26

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:11:23

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:39:26

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:11:23

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:39:26

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:11:23

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:39:26

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:11:23

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:39:26

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:11:23

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	13 Oct 2020 14:39:26

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:11:23

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:39:26

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:11:23

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:39:26

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:11:23

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:39:26

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:11:23

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:39:26

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:11:23

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:39:26

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:11:23

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	(b) (4), (b) (6)	13 Oct 2020 14:40:25

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:11:23

[Date](#)

Audit	User	Time (GMT)
User entered '2 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 14:40:25

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:11:23

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 14:40:25

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:11:23

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '100'	(b) (4), (b) (6)	13 Oct 2020 14:40:25

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:11:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	13 Oct 2020 14:40:25

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:11:23

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.9' F	(b) (4), (b) (6)	13 Oct 2020 14:40:25

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:11:23

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:40:25

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:11:23

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:40:25

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:11:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:40:25

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:11:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:40:25

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:11:23

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:40:25

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:11:23

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:40:25

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:11:23

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:40:25

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:11:23

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:40:25

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:11:23

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:40:25

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:11:23

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:40:25

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:11:23

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Severe (Severe)'	(b) (4), (b) (6)	13 Oct 2020 14:40:25

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:11:23

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:40:25

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:11:23

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:40:25

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:11:23

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:40:25

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:11:23

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:40:25

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:11:23

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:40:25

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:11:23

[Date of Visit](#)

Audit	User	Time (GMT)
User closed query ' Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 30 SEP 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC.As per the CCG v 2, please add illness folder using ADD EVENT DROP Down and review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 05:29:38
Query ' Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 30 SEP 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC.As per the CCG v 2, please add illness folder using ADD EVENT DROP Down and review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 19:22:50
User opened query ' Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 30 SEP 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC.As per the CCG v 2, please add illness folder using ADD EVENT DROP Down and review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 09:19:00
User entered '30 Sep 2020'	(b) (4), (b) (6)	13 Oct 2020 14:40:55

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:11:23

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 14:40:55

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:11:23

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 19:36:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 19:36:59
User entered 'No (N)' reason for change: Data Entry Error	Cynthia Strout (b) (4) (b) (4)	13 Oct 2020 19:36:59
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 19:35:14
User entered empty; reason for change Data Entry Error	Cynthia Strout (b) (4) (b) (4)	13 Oct 2020 19:35:14
User entered 'No (N)'	(b) (4), (b) (6) (b) (4)	13 Oct 2020 14:40:55

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:11:23

[Date of Test](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	(b) (4), (b) (6)	13 Oct 2020 14:40:55

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:11:23

[Type of Test Performed](#)

Audit	User	Time (GMT)
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	13 Oct 2020 14:40:55

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:11:23

[Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 14:40:55

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:11:23

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 14:40:55

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:11:23

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 14:40:55

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:11:23

[CLIA Certified?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 14:40:55

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:11:23

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Oct 2020 14:40:55

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:11:23

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 14:17:57

US3672333

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 11:11:23

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	16 Nov 2020 22:23:24

US3672333

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 11:11:23

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 22:23:24

US3672333

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 11:11:23

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	(b) (4), (b) (6)	16 Nov 2020 22:23:24

US3672333

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 11:11:23

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	16 Nov 2020 22:23:24

US3672333

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 11:11:23

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	16 Nov 2020 22:23:24

US3672333

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 11:11:23

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 22:23:24

US3672333

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 11:11:23

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	16 Nov 2020 22:23:24

US3672333

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 11:11:23

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	16 Nov 2020 22:23:24

US3672333

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 11:11:23

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 22:23:24

US3672333

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 11:11:23

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	16 Nov 2020 22:23:24

US3672333

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 11:11:23

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	16 Nov 2020 22:23:24

US3672333

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 11:11:23

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 22:23:24

US3672333

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 11:11:23

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	16 Nov 2020 22:23:24

US3672333

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 11:11:23

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	16 Nov 2020 22:23:24

US3672333

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 11:11:23

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 22:23:24

US3672333

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 11:11:23

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	16 Nov 2020 22:23:24

US3672333

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 11:11:23

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	16 Nov 2020 22:23:24

US3672333

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 11:11:23

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 22:23:24

US3672333

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 11:11:23

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	16 Nov 2020 22:23:24

US3672333

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 11:11:23

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	16 Nov 2020 22:23:24

US3672333

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 11:11:23

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 22:23:24

US3672333

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:11:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 22:21:03

US3672333

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '30 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 22:22:40
User entered '20 Sep 2020'	(b) (4), (b) (6)	16 Nov 2020 22:21:03

US3672333

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	16 Nov 2020 22:21:03

US3672333

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:11:23

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	16 Nov 2020 22:21:03

US3672333

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 22:21:43

US3672333

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	16 Nov 2020 22:22:54
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	16 Nov 2020 22:22:54
User entered '30 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 22:22:54
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	16 Nov 2020 22:22:40
User entered '20 Sep 2020'	(b) (4), (b) (6)	16 Nov 2020 22:21:43

US3672333

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:55'	(b) (4), (b) (6)	16 Nov 2020 22:21:43

US3672333

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '30 Sep 2020 10:55'	System	16 Nov 2020 22:22:54
User entered '20 Sep 2020 10:55'	System	16 Nov 2020 22:21:43

US3672333

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '160.0' cm	(b) (4), (b) (6)	16 Nov 2020 22:21:43
DataPoint set to visible.	System	16 Nov 2020 22:21:03

US3672333

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

Weight (xxx.x)

Audit	User	Time (GMT)
User entered '78.7' kg	(b) (4), (b) (6)	16 Nov 2020 22:21:43
DataPoint set to visible.	System	16 Nov 2020 22:21:03

US3672333

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.5' F	(b) (4), (b) (6)	16 Nov 2020 22:21:43

US3672333

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	16 Nov 2020 22:21:43

US3672333

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 22:21:43

US3672333

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '68'	(b) (4), (b) (6)	16 Nov 2020 22:21:43

US3672333

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	16 Nov 2020 22:21:43

US3672333

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '20'	(b) (4), (b) (6)	16 Nov 2020 22:21:43

US3672333

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	16 Nov 2020 22:21:43

US3672333

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '102'	(b) (4), (b) (6)	16 Nov 2020 22:21:43

US3672333

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Nov 2020 22:21:43

US3672333

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '73'	(b) (4), (b) (6)	16 Nov 2020 22:21:43

US3672333

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Nov 2020 22:21:43

US3672333

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:11:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 22:21:51

US3672333

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:11:23

[Date of examination \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	16 Nov 2020 22:22:40
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	16 Nov 2020 22:22:33
User entered '30 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 22:22:33
User entered '20 Sep 2020'	(b) (4), (b) (6)	16 Nov 2020 22:21:51

US3672333

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 11:11:23

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 22:22:02

US3672333

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 11:11:23

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 22:22:09
User entered '20 Sep 2020'	(b) (4), (b) (6)	16 Nov 2020 22:22:02

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 11:11:23

[Visit Date](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 15:38:34
User entered '23 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 14:16:23

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 11:11:23

[Physical Exam](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 14:16:23

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 11:11:23

[Vital Signs](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	25 Sep 2020 14:16:23

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 11:11:23

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	25 Sep 2020 14:16:23

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 11:11:23

[Pregnancy Test](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	25 Sep 2020 14:16:23

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 14:17:03

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '30 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 15:38:50
User entered '23 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 14:17:03

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '15:15'	(b) (4), (b) (6)	25 Sep 2020 14:17:03

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '30 Sep 2020 15:15'	System	26 Oct 2020 15:38:50
User entered '23 Sep 2020 15:15'	System	25 Sep 2020 14:17:03

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.4' F	(b) (4), (b) (6)	25 Sep 2020 14:17:03

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	25 Sep 2020 14:17:03

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 14:17:03

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '78'	(b) (4), (b) (6)	25 Sep 2020 14:17:03

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	25 Sep 2020 14:17:03

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '17'	(b) (4), (b) (6)	25 Sep 2020 14:17:03

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	25 Sep 2020 14:17:03

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '137'	(b) (4), (b) (6)	25 Sep 2020 14:17:03

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Sep 2020 14:17:03

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '89'	(b) (4), (b) (6)	25 Sep 2020 14:17:03

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:23

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Sep 2020 14:17:03

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:11:23

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 14:17:20

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:11:23

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Date of Test is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	26 Oct 2020 15:38:57
User entered '30 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 15:38:57
User opened query 'Date of Test is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	26 Oct 2020 15:38:34
User entered '23 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 14:17:20

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:11:23

[Test performed](#)

Audit	User	Time (GMT)
User entered 'Urine (URINE)'	(b) (4), (b) (6)	25 Sep 2020 14:17:20

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:11:23

[Result](#)

Audit	User	Time (GMT)
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	25 Sep 2020 14:17:20

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:11:23

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 14:17:20

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:11:23

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 14:17:20

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:11:23

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 14:17:20

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 14:17:20

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:11:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Recon: GCL received a sample for Immunogenicity assessment for V2D29 dated 23 SEP 2020, however this date matches an unscheduled visit in EDC. please confirm the V2D29 immunogenicity sample belongs to the unscheduled EDC visit.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 15:46:54
Query 'Per GCL Lab Recon: GCL received a sample for Immunogenicity assessment for V2D29 dated 23 SEP 2020, however this date matches an unscheduled visit in EDC. please confirm the V2D29 immunogenicity sample belongs to the unscheduled EDC visit.' answered with 'date of illness visit corrected' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 15:39:10
User opened query 'Per GCL Lab Recon: GCL received a sample for Immunogenicity assessment for V2D29 dated 23 SEP 2020, however this date matches an unscheduled visit in EDC. please confirm the V2D29 immunogenicity sample belongs to the unscheduled EDC visit.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 13:44:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 14:17:48

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:11:23

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	26 Oct 2020 15:38:34
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	26 Oct 2020 15:38:25
User entered '30 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 15:38:25
User entered '23 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 14:17:48

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '15:35'	(b) (4), (b) (6)	25 Sep 2020 14:17:48

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '30 Sep 2020 15:35'	System	26 Oct 2020 15:38:25
User entered '23 Sep 2020 15:35'	System	25 Sep 2020 14:17:48

US3672333

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:11:23

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Patty Howenstine (b) (4) (b) (4)	14 Sep 2020 17:38:42

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:23

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 06:10:32
Query 'Per DM CLR: Please review and specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. Otherwise, clarify.' answered with 'PLEASE READ THE TERM FOR THE ADVERSE EVENT AS IT CLEARLY NOTES THE LATERALITY' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 00:13:51
User opened query 'Per DM CLR: Please review and specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 00:07:05
User closed query 'Per DM CLR: Please review and update AE term to reflect specific body location of LYMPHADENOPHTHY. Please reconcile with the ConMed eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 19:21:25
Query 'Per DM CLR: Please review and update AE term to reflect specific body location of LYMPHADENOPHTHY. Please reconcile with the ConMed eCRF so there is an appropriate match. ' answered with 'Updated per query.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 20:28:07
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy axillary - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 14:43:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 14:43:35
Data point term sent to Coder	System	21 Oct 2020 13:30:31
Coding entries removed.	(b) (4), (b) (6)	21 Oct 2020 13:29:36
User entered 'LYMPHADENOPATHY R Underarm' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 13:29:36

v6.020 DTW (1102)

1390 of 1499

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:23

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review and update AE term to reflect specific body location of LYMPHADENOPATHY. Please reconcile with the ConMed eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 11:37:15
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 17:41:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 17:41:50
Data point term sent to Coder	System	14 Sep 2020 17:40:52
User entered 'LYMPHADENOPATHY'	Patty Howenstine (b) (4) (b) (4)	14 Sep 2020 17:40:39

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:23

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Patty Howenstine (b) (4) (b) (4)	14 Sep 2020 17:40:39

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:23

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR - RQ: Site's response noted. However, solicited reactions are only reported as AE if it meets AE reporting criteria per Protocol section 8.3.4. This AE started after Day 7 (onwards) post vaccination, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 18:47:44
Query 'Per DM CLR - RQ: Site's response noted. However, solicited reactions are only reported as AE if it meets AE reporting criteria per Protocol section 8.3.4. This AE started after Day 7 (onwards) post vaccination, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to No. Else, provide clarification.'	(b) (4), (b) (6)	07 Nov 2020 00:17:46
answered with 'UPDATED' (Site from DM).		
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 00:17:39
User opened query 'Per DM CLR - RQ: Site's response noted. However, solicited reactions are only reported as AE if it meets AE reporting criteria per Protocol section 8.3.4. This AE started after Day 7 (onwards) post vaccination, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 00:08:05
User closed query 'Per DM CLR: Please confirm if this pertains to Underarm gland swelling. If yes, note that solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started at after Day 7 (onwards), review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 19:24:07

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:23

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please confirm if this pertains to Underarm gland swelling. If yes, note that solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started at after Day 7 (onwards), review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification.' answered with 'Event took place greater than 7 days after an injection' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 15:33:08
User opened query 'Per DM CLR: Please confirm if this pertains to Underarm gland swelling. If yes, note that solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started at after Day 7 (onwards), review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 11:37:21
User entered 'Yes (Y)'	Patty Howenstine (b) (4)	14 Sep 2020 17:40:39

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:23

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Patty Howenstine (b) (4) (b) (4)	14 Sep 2020 17:40:39

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '7 Sep 2020'	Patty Howenstine (b) (4) (b) (4)	14 Sep 2020 17:40:39

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered empty.	Patty Howenstine (b) (4) (b) (4)	14 Sep 2020 17:40:39

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:23

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 17:40:39

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:23

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Patty Howenstine (b) (4) (b) (4)	14 Sep 2020 17:40:39

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:23

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Patty Howenstine (b) (4) (b) (4)	14 Sep 2020 17:40:39

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered empty.	Patty Howenstine (b) (4) (b) (4)	14 Sep 2020 17:40:39

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:23

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 17:40:39

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:23

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Patty Howenstine (b) (4) (b) (4)	14 Sep 2020 17:40:39

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:23

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Patty Howenstine (b) (4) (b) (4)	14 Sep 2020 17:40:39

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:23

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Patty Howenstine (b) (4) (b) (4)	14 Sep 2020 17:40:39

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:23

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Patty Howenstine (b) (4) (b) (4)	14 Sep 2020 17:40:39

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Patty Howenstine (b) (4) (b) (4)	14 Sep 2020 17:40:39

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:23

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Patty Howenstine (b) (4) (b) (4)	14 Sep 2020 17:40:39

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:23

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Patty Howenstine (b) (4) (b) (4)	14 Sep 2020 17:40:39

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:23

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Patty Howenstine (b) (4) (b) (4)	14 Sep 2020 17:40:39

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:23

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Patty Howenstine (b) (4) (b) (4)	14 Sep 2020 17:40:39

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Patty Howenstine (b) (4) (b) (4)	14 Sep 2020 17:40:39

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Patty Howenstine (b) (4) (b) (4)	14 Sep 2020 17:40:39

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:23

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Patty Howenstine (b) (4) (b) (4)	14 Sep 2020 17:40:39

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:23

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 17:41:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 17:41:06
User entered 'Related (RELATED)' reason for change: Data Entry Error	Patty Howenstine (b) (4)	14 Sep 2020 17:41:06
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 17:40:39
User entered empty.	Patty Howenstine (b) (4)	14 Sep 2020 17:40:39

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:23

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 17:41:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 17:41:06
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Patty Howenstine (b) (4)	14 Sep 2020 17:41:06
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 17:40:39
User entered empty.	Patty Howenstine (b) (4)	14 Sep 2020 17:40:39

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:23

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 17:41:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 17:41:06
User entered 'None (NONE)' reason for change: Data Entry Error	Patty Howenstine (b) (4)	14 Sep 2020 17:41:06
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 17:40:39
User entered empty.	Patty Howenstine (b) (4)	14 Sep 2020 17:40:39

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:23

[None](#)

Audit	User	Time (GMT)
User entered '1'	Patty Howenstine (b) (4) (b) (4)	14 Sep 2020 17:40:39

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:23

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Patty Howenstine (b) (4) (b) (4)	14 Sep 2020 17:40:39

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:23

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Patty Howenstine (b) (4) (b) (4)	14 Sep 2020 17:40:39

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:23

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 17:41:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 17:41:06
User entered 'Unknown (UNKNOWN)' reason for change: Data Entry Error	Patty Howenstine (b) (4)	14 Sep 2020 17:41:06
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 17:40:39
User entered empty.	Patty Howenstine (b) (4)	14 Sep 2020 17:40:39

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:23

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Patty Howenstine (b) (4) (b) (4)	14 Sep 2020 17:40:39

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:23

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Patty Howenstine (b) (4) (b) (4)	14 Sep 2020 17:40:39

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:23

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	14 Sep 2020 17:40:39

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:23

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Sep 2020 17:40:39

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:23

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' answered with 'Subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 20:22:19
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 20:20:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 20:20:56
Data point term sent to Coder	System	24 Nov 2020 20:19:35
Coding entries removed.	(b) (4), (b) (6)	24 Nov 2020 20:18:56
User entered 'UPPER RESPIRATORY INFECTION (URI)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 20:18:56
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 12:55:07
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 15:24:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 15:24:37
Data point term sent to Coder	System	14 Oct 2020 15:02:19
User entered 'Upper Respiratory Infection URI'	(b) (4), (b) (6)	14 Oct 2020 15:01:35

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:23

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 15:01:35

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:23

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 15:01:35

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:23

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 15:01:35

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '24 Sep 2020'	(b) (4), (b) (6)	14 Oct 2020 15:01:35

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 15:01:35

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:23

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 15:01:35

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:23

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 15:01:35

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:23

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	(b) (4), (b) (6)	14 Oct 2020 15:01:35

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 15:01:35

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:23

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 15:01:35

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:23

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	14 Oct 2020 15:01:35

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:23

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 15:01:35

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:23

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 15:01:35

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:23

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 15:01:35

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 15:01:35

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:23

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 15:01:35

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:23

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 15:01:35

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:23

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 15:01:35

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:23

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 15:01:35

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 15:01:35

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 15:01:35

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:23

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 15:01:35

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:23

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	14 Oct 2020 15:01:35

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:23

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	14 Oct 2020 15:01:35

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:23

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	24 Nov 2020 20:21:16
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).	System	24 Nov 2020 20:21:16
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	18 Nov 2020 21:15:36
User closed query 'Per CDM: The reason provided for study treatment not given on Exposure (V2D29) page is 'NO SWAB RESULT FOUND FROM DAY 1' However, 'Delayed' is recorded here. Please confirm the next dose of IP is given or not and update the respective forms accordingly or else provide clarification. Thank you. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 23:47:46
Query 'Per CDM: The reason provided for study treatment not given on Exposure (V2D29) page is 'NO SWAB RESULT FOUND FROM DAY 1' However, 'Delayed' is recorded here. Please confirm the next dose of IP is given or not and update the respective forms accordingly or else provide clarification. Thank you. ' answered with 'subject was never given the second dosage' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 15:35:27
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 15:35:09
User opened query 'Per CDM: The reason provided for study treatment not given on Exposure (V2D29) page is 'NO SWAB RESULT FOUND FROM DAY 1' However, 'Delayed' is recorded here. Please confirm the next dose of IP is given or not and update the respective forms accordingly or else provide clarification. Thank you. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 05:40:46
User entered 'Dose Delayed (DOSE DELAYED)'	(b) (4), (b) (6)	14 Oct 2020 15:01:35

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:23

[None](#)

Audit	User	Time (GMT)
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	21 Oct 2020 13:35:01
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 13:35:01
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	14 Oct 2020 15:01:35
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 15:01:35

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:23

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 15:01:35

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:23

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 15:01:35

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:23

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 13:35:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 13:35:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 13:35:01
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 15:01:35
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 15:01:35

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:23

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 15:01:35

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:23

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 15:01:35

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:23

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	14 Oct 2020 15:01:35

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:23

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Oct 2020 15:01:35

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:11:23

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 18:41:37

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:23

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS, PRODUCT: ETONOGESTREL, PRODUCTSYNONYM: NEXPLANON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 13:38:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 13:38:38
Data point term sent to Coder	System	21 Oct 2020 13:37:39
Coding entries removed.	(b) (4), (b) (6)	21 Oct 2020 13:37:24
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS, PRODUCT: ETONOGESTREL, PRODUCTSYNONYM: NEXPLANON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 18:43:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 18:43:51
Data point term sent to Coder	System	28 Aug 2020 18:43:07
User entered 'Nexplanon'	(b) (4), (b) (6)	28 Aug 2020 18:42:25

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:42:25

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:23

[Indication](#)

Audit	User	Time (GMT)
User entered 'Contraception'	(b) (4), (b) (6)	28 Aug 2020 18:42:25

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:23

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose for this medication. Please verify if the number of implant is a more appropriate recording. Please review and correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 19:25:02
Query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose for this medication. Please verify if the number of implant is a more appropriate recording. Please review and correct the dosage or provide explanation for alternate dosage.' answered with 'Updated dosage' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 13:49:36
User entered '68' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 13:49:27
User opened query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose for this medication. Please verify if the number of implant is a more appropriate recording. Please review and correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	04 Oct 2020 23:30:23
User entered '40'	(b) (4), (b) (6)	28 Aug 2020 18:42:25

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:23

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 13:49:27
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 13:36:07
User entered 'ug (ug)'	(b) (4), (b) (6)	28 Aug 2020 18:42:25

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 13:49:27
User entered 'mcg' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 13:36:07
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:42:25

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:23

[Frequency](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 19:25:37
Query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' answered with 'Updated per query.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 20:26:56
User entered 'other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 20:26:46
User opened query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Oct 2020 23:30:39
User entered 'once daily (QD)'	(b) (4), (b) (6)	28 Aug 2020 18:42:25

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered 'Every 3 years' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 20:26:46
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:42:25

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:23

[Route of administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Verify if "SUBDERMAL" is a more appropriate recording. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 19:25:32
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Verify if "SUBDERMAL" is a more appropriate recording. Please update route as appropriate.'	(b) (4), (b) (6)	21 Oct 2020 13:38:22
answered with 'Subdermal updated.' (Site from DM).		
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 13:37:24
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Verify if "SUBDERMAL" is a more appropriate recording. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Oct 2020 23:30:31
User entered 'Transdermal (TRANSDERMAL)'	(b) (4), (b) (6)	28 Aug 2020 18:42:25

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered 'Subdermal' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 13:37:24
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:42:25

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '26 Nov 2018'	(b) (4), (b) (6)	28 Aug 2020 18:42:25

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 18:42:25

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:23

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 18:42:25

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:42:25

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:42:25

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 20:26:46
User entered '1'	System	28 Aug 2020 18:42:25

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 20:26:46
User entered '1'	System	28 Aug 2020 18:42:25

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 20:26:46
User entered '804 (804)'	System	28 Aug 2020 18:42:25

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:23

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 20:34:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 20:34:04
Data point term sent to Coder	System	19 Nov 2020 20:32:41
User entered 'influenza vaccine'	(b) (4), (b) (6) (b) (4)	19 Nov 2020 20:32:15

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 20:32:15

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:23

[Indication](#)

Audit	User	Time (GMT)
User entered 'influenza prophylaxis'	(b) (4), (b) (6)	19 Nov 2020 20:32:15

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:23

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	19 Nov 2020 20:32:15

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:23

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	(b) (4), (b) (6)	19 Nov 2020 20:32:15

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:23

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered 'injection'	(b) (4), (b) (6)	19 Nov 2020 20:32:15

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:23

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	(b) (4), (b) (6)	19 Nov 2020 20:32:15

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:32:15

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:23

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	19 Nov 2020 20:32:15

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:32:15

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered '9 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 20:32:15

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 20:32:15

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:23

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 20:32:15

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '9 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 20:32:15

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 20:32:15

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 20:32:15

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 20:32:15

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 20:32:15

US3672333

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:11:23

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	(b) (4), (b) (6)	26 Oct 2020 15:37:00

US3672333

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:11:23

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 20:21:16
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 21:15:36
User entered 'AE (specify) (ADVERSE EVENT)'	(b) (4), (b) (6)	26 Oct 2020 15:37:00

US3672333

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:11:23

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

Audit	User	Time (GMT)
User entered 'AE#1 and dosing discontinued due to day 1 swab never found.' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 20:21:39
User closed query 'Per CDM: Primary reason for dosing discontinuation is 'AE ' However, specification is not matching with the Primary reason. Per CCG pg.42 If reason for discontinuation is 'Adverse Event, SAE, Physician Decision, Withdrawal of Consent, Protocol Deviation or Other Please consider to the Specify reason. Please confirm and update appropriately. Else clarify Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 16:24:26
Query 'Per CDM: Primary reason for dosing discontinuation is 'AE ' However, specification is not matching with the Primary reason. Per CCG pg.42 If reason for discontinuation is 'Adverse Event, SAE, Physician Decision, Withdrawal of Consent, Protocol Deviation or Other Please consider to the Specify reason. Please confirm and update appropriately. Else clarify Thank you.' answered with 'updated to OTHER' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 21:15:44
User opened query 'Per CDM: Primary reason for dosing discontinuation is 'AE ' However, specification is not matching with the Primary reason. Per CCG pg.42 If reason for discontinuation is 'Adverse Event, SAE, Physician Decision, Withdrawal of Consent, Protocol Deviation or Other Please consider to the Specify reason. Please confirm and update appropriately. Else clarify Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 08:46:55
User entered 'no second dosage given due to no day 1 swab found'	(b) (4), (b) (6)	26 Oct 2020 15:37:00