

US3552497 (Prod: Saint Louis University)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:35:00

All time stamps listed in this document are displayed in GMT

US3552497

Form: Participant Creation

Generated On: 26 Nov 2020 09:35:00

[Participant ID](#)

US3552497

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

US3552497

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:35:00

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

US3552497

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:00

Date of Birth (MMM yyyy)	(b) (6) 1998
Age	22
Age Units	YEARS
Age (Derived)	22
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	False
Black	False
Asian	True
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

US3552497

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:35:00

Date of Informed Consent (<i>dd MMM yyyy</i>)	26 SEP 2020
Month and Year of Informed Consent (derived)	SEP 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

US3552497

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:35:00

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3552497

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:35:00

Were any significant conditions reported?

Yes ☒

No ☐

US3552497

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:35:00

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN AUG 2015
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)	AUG 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

US3552497

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:35:00

Condition	HYPOTHYROIDISM HASHIMOTO DX
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN MAR 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	MAR 2015
Stop Year (derived)	2015

US3552497

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:35:00

Condition	THYROIDECTOMY
Start date (dd MMM yyyy)	UN MAR 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN MAR 2015
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2015
Start Year (derived)	2015
Stop Month and Year (derived)	MAR 2015
Stop Year (derived)	2015

US3552497

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:35:00

Condition	ALLERGY TO THIAMAZOLE
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

US3552497

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:35:00

Condition	CHILDHOOD ASTHMA
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2006
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JAN 2006
Stop Year (derived)	2006

US3552497

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:35:00

Condition	KELOID LESIONS ON CHEST
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

US3552497

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:00

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	26 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	13:09 (24 HR)
Vital Signs Date and Time (derived)	26 SEP 2020 13:09
Height (<i>xxx.x</i>)	65 in
Weight (<i>xxx.x</i>)	195 lb
BMI (<i>xxx.x</i>)	32.51755 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)	

US3552497

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:00

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 SEP 2020

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

US3552497

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:35:00

Date of assessment (*dd MMM yyyy*) 26 SEP 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

US3552497

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:35:00

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

US3552497

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:00

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 OCCUPATIONAL THERAPY
STUDENT, GROCERY
SHOPPING, NAIL SALON, DINE
(OUTDOORS)

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

v6.020 DTW (1102)

17 of 1343

US3552497

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:00

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	True
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)	False
Other	False
Specify	

US3552497

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:35:00

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

US3552497

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:00

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

What was the participant's randomization number? 115802

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 ☒

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:35:00

Height	ND - Not Done
Weight	ND - Not Done

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:00

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 SEP 2020
Time of assessment (00:00-23:59)	13:09 (24 HR)
Vital Signs Date and Time (derived)	26 SEP 2020 13:09
Temperature (xxx.x)	98.8 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:00

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 SEP 2020
Time of assessment (00:00-23:59)	14:55 (24 HR)
Vital Signs Date and Time (derived)	26 SEP 2020 14:55
Temperature (xxx.x)	98.4 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3552497

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:00

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.

US3552497

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:35:00

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) _____

US3552497

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:00

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 SEP 2020
What was the treatment time? (00:00-23:59)	14:25 (24 HR)
Treatment Date and Time (derived)	26 SEP 2020 14:25
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

US3552497

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:00

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	26 SEP 2020
Collection time (<i>00:00-23:59</i>)	13:45 (24 HR)
Collection date and time (derived)	26 SEP 2020 13:45

US3552497

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:35:00

Collection date (<i>dd MMM yyyy</i>)			26 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:50	26 SEP 2020 13:50
Nasopharyngeal Swab 2	No		

US3552497

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:35:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:35:00

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 14:54

PC Open Date & Time

26 SEP 2020 14:45

PC Close Date & Time

26 SEP 2020 17:15

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.9 °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 SEP 2020 19:31
PC Open Date & Time	26 SEP 2020 18:10
PC Close Date & Time	27 SEP 2020 11:59

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:35:00

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 SEP 2020 13:09

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 17:57

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 13:56

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:35:00

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 SEP 2020 22:43

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:35:00

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 00:04

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

02 OCT 2020 21:57

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:35:00

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 SEP 2020 14:54

PC Open Date & Time

26 SEP 2020 14:45

PC Close Date & Time

26 SEP 2020 17:15

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:35:00

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

5

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

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 SEP 2020 19:31

PC Open Date & Time

26 SEP 2020 18:10

PC Close Date & Time

27 SEP 2020 11:59

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:35:00

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 SEP 2020 13:10

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:35:00

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 SEP 2020 17:58

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:35:00

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 SEP 2020 13:56

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:35:00

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 SEP 2020 22:43

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:35:00

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

02 OCT 2020 00:04

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:35:00

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

02 OCT 2020 21:57

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:35:00

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

No ☒

Yes ☐

PC Time stamp	26 SEP 2020 14:55
PC Open Date & Time	26 SEP 2020 14:45
PC Close Date & Time	26 SEP 2020 17:15

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:35:00

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

No ☒

Yes ☐

PC Time stamp	26 SEP 2020 19:31
PC Open Date & Time	26 SEP 2020 18:10
PC Close Date & Time	27 SEP 2020 11:59

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:35:00

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 ☒

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:35:00

Yes ☐	
PC Time stamp	27 SEP 2020 13:11
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:35:00

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 ☒

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:35:00

Yes ☐	
PC Time stamp	28 SEP 2020 17:58
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:35:00

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 ☒

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:35:00

Yes ☐	
PC Time stamp	29 SEP 2020 13:56
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:35:00

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 ☒

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:35:00

Yes ☐	
PC Time stamp	30 SEP 2020 22:44
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:35:00

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 ☒

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:35:00

Yes ☐	
PC Time stamp	02 OCT 2020 00:05
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:35:00

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 ☒

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:35:00

Yes ☐	
PC Time stamp	02 OCT 2020 21:57
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3552497

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552497

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552497

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552497

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552497

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552497

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552497

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:00

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	29 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:00

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	29 OCT 2020
Time of assessment (00:00-23:59)	15:30 (24 HR)
Vital Signs Date and Time (derived)	29 OCT 2020 15:30
Temperature (xxx.x)	99.0 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	22 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:00

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	

US3552497

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:00

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 OCT 2020

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

US3552497

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:35:00

Was the pregnancy test performed?	Yes ☒
	No ☐
Date of test (<i>dd MMM yyyy</i>)	29 OCT 2020
Test performed	Urine ☒
	Serum ☐
Result	Positive ☐
	Negative ☒
Was FSH sample collected?	Yes ☐
	No ☒
Collection date	
Collection time	
Collection date and time (derived)	

US3552497

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:35:00

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 RASH TO LEFT ARM

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? _____

US3552497

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:00

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	29 OCT 2020
Collection time (<i>00:00-23:59</i>)	15:47 (24 HR)
Collection date and time (derived)	29 OCT 2020 15:47

US3552497

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:35:00

Collection date (dd MMM yyyy)			29 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:12	29 OCT 2020 16:12
Nasopharyngeal Swab 2	No		

US3552497

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552497

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552497

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552497

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552497

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552497

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:00

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

US3552497

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552497

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:00

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	20 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3552497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:00

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)	

US3552497

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:00

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.

US3552497

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:00

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	20 NOV 2020
Collection time (<i>00:00-23:59</i>)	08:42 (24 HR)
Collection date and time (derived)	20 NOV 2020 08:42

US3552497

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:00

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

27 NOV 2020 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

04 DEC 2020 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

11 DEC 2020 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

18 DEC 2020 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

25 DEC 2020 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

01 JAN 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

08 JAN 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

15 JAN 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

22 JAN 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

29 JAN 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

05 FEB 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

12 FEB 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

19 FEB 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

26 FEB 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

05 MAR 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

12 MAR 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

19 MAR 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

26 MAR 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

02 APR 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

09 APR 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

16 APR 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

23 APR 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

30 APR 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

07 MAY 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

25 JUN 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

09 JUL 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

16 JUL 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

23 JUL 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

30 JUL 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

20 AUG 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

27 AUG 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

17 SEP 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

08 OCT 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

15 OCT 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

22 OCT 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

29 OCT 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

19 NOV 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

10 DEC 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

17 DEC 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

24 DEC 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

31 DEC 2021 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

21 JAN 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

18 FEB 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

25 FEB 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

11 MAR 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

18 MAR 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

08 APR 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

15 APR 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

22 APR 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

29 APR 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

20 MAY 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

27 MAY 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

17 JUN 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

24 JUN 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

01 JUL 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

08 JUL 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

15 JUL 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

22 JUL 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

29 JUL 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

19 AUG 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

26 AUG 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

16 SEP 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

23 SEP 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

30 SEP 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

14 OCT 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

21 OCT 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

28 OCT 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

04 NOV 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

11 NOV 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

18 NOV 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

25 NOV 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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 ☐

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

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

[Patient Cloud Close Date & Time](#)

02 DEC 2022 23:59

US3552497

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:35:00

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
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 ☐

US3552497

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:35:00

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3552497

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:35:00

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:00

AEID	
Adverse event	RASH TO LEFT ARM
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)	03 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	06 OCT 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	
Persistent or significant disability or incapacity	False
v6.020 DTW (1102)	303 of 1343

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:00

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)	

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:35:00

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

Yes ☒

No ☐

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

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:35:00

Name of Medication	LILETTA IUD
Prophylaxis	Yes ☒ No ☐
Indication	BIRTH CONTROL
Dose per administration	52
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:35:00

	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)	UN UNK 2017	
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	☐

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:35:00

Name of Medication	LEVOTHYROXINE
Prophylaxis	Yes ☐ No ☒
Indication	HYPOTHYROIDISM
Dose per administration	175/150
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:35:00

	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)	UN	UNK 2016
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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:35:00

Name of Medication	VITAMIN D
Prophylaxis	Yes ☒ No ☐
Indication	HEALTH PROMOTION
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☒ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:35:00

	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)	UN	UNK 2015
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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:35:00

Name of Medication	BIOTIN
Prophylaxis	Yes ☒ No ☐
Indication	HEALTH PROMOTION
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☒ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:35:00

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)	UN MAY 2020
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)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:35:00

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	CC
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 ☒

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:35:00

	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)		13 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		13 OCT 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 ☐

US3552497

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:35:00

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3552497

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:35:00

Date of dosing discontinuation (dd MMM yyyy)

29 OCT 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

US3552497

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:35:00

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

US3552497 (Prod: Saint Louis University)

US3552497

Form: Participant Creation

Generated On: 26 Nov 2020 09:35:00

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3552497'	RWS_ENDPOINT ENDPOINT (b) (4) 	26 Sep 2020 18:17:34

US3552497

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:35:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:04:41

US3552497

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '26 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	26 Sep 2020 18:17:35

US3552497

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:04:41

US3552497

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:35:00

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	28 Sep 2020 12:04:41

US3552497

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered (b) (6) 1998'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	26 Sep 2020 18:17:36

US3552497

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:00

[Age](#)

Audit	User	Time (GMT)
User entered '22'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:05:17

US3552497

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:00

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	28 Sep 2020 12:05:17

US3552497

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:00

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '22'	System	26 Sep 2020 19:13:17

US3552497

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:00

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:05:17

US3552497

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:00

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Stanley Dublin (b) (4)	28 Sep 2020 12:05:17

US3552497

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:00

[White](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:05:17

US3552497

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:00

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:05:17

US3552497

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:00

[Asian](#)

Audit	User	Time (GMT)
User entered '1'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:05:17

US3552497

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:00

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:05:17

US3552497

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:00

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:05:17

US3552497

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:00

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:05:17

US3552497

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:00

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:05:17

US3552497

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:00

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:05:17

US3552497

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:00

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:05:17

US3552497

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '26 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 19:13:17

US3552497

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	26 Sep 2020 19:13:17

US3552497

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '2020'	System	26 Sep 2020 19:13:17

US3552497

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:35:00

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	26 Sep 2020 19:13:17

US3552497

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 19:13:17

US3552497

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 19:13:17

US3552497

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:35:00

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 19:13:17

US3552497

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:35:00

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Sep 2020 19:13:17

US3552497

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:35:00

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	26 Sep 2020 18:17:35

US3552497

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:35:00

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 19:13:22

US3552497

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 19:13:22

US3552497

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:35:00

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:07:01

US3552497

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:35:00

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 12:08:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 12:08:46
Data point term sent to Coder	System	28 Sep 2020 12:07:44
User entered 'hypothyroidism'	Stanley Doublin (b) (4)	28 Sep 2020 12:07:43
	(b) (4)	

US3552497

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'un Aug 2015'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:07:43

US3552497

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:35:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:07:43

US3552497

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:35:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:07:43

US3552497

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:07:43

US3552497

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:35:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:07:43

US3552497

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'Aug 2015'	System	28 Sep 2020 12:07:43

US3552497

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '2015'	System	28 Sep 2020 12:07:43

US3552497

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 12:07:43

US3552497

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 12:07:43

US3552497

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:35:00

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Acute and chronic thyroiditis, PT: Autoimmune thyroiditis, LLT: Hashimoto's disease - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 00:11:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 00:11:35
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 14:56:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 14:56:44
Data point term sent to Coder	System	28 Sep 2020 12:08:45
User entered 'hypothyroidism hashimoto dx'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:08:41

US3552497

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2014'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:08:41

US3552497

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:35:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:08:41

US3552497

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:35:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:08:41

US3552497

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'un Mar 2015'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:08:41

US3552497

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:35:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:08:41

US3552497

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	28 Sep 2020 12:08:41

US3552497

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '2014'	System	28 Sep 2020 12:08:41

US3552497

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'Mar 2015'	System	28 Sep 2020 12:08:41

US3552497

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '2015'	System	28 Sep 2020 12:08:41

US3552497

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:35:00

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Endocrine gland therapeutic procedures, HLT: Thyroid therapeutic procedures, PT: Thyroidectomy, LLT: Thyroidectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 12:10:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 12:10:38
Data point term sent to Coder	System	28 Sep 2020 12:09:45
User entered 'thyroidectomy'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:09:12

US3552497

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'un Mar 2015'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:09:12

US3552497

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:35:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:09:12

US3552497

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:35:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:09:12

US3552497

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'un Mar 2015'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:09:12

US3552497

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:35:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:09:12

US3552497

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'Mar 2015'	System	28 Sep 2020 12:09:12

US3552497

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '2015'	System	28 Sep 2020 12:09:12

US3552497

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'Mar 2015'	System	28 Sep 2020 12:09:12

US3552497

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '2015'	System	28 Sep 2020 12:09:12

US3552497

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:35:00

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 14:41:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 14:41:37
Data point term sent to Coder	System	28 Sep 2020 12:10:46
User entered 'allergy to thiamazole'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:10:12

US3552497

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:10:12

US3552497

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:35:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:10:12

US3552497

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:35:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:10:12

US3552497

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:10:12

US3552497

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:35:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:10:12

US3552497

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	28 Sep 2020 12:10:12

US3552497

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '2015'	System	28 Sep 2020 12:10:12

US3552497

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 12:10:12

US3552497

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 12:10:12

US3552497

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:35:00

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Childhood asthma, LLT: Childhood asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 12:12:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 12:12:47
Data point term sent to Coder	System	28 Sep 2020 12:11:46
User entered 'childhood asthma'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:10:48

US3552497

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2002'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:10:48

US3552497

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:35:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:10:48

US3552497

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:35:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:10:48

US3552497

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2006'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:10:48

US3552497

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:35:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:10:48

US3552497

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'Jan 2002'	System	28 Sep 2020 12:10:48

US3552497

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '2002'	System	28 Sep 2020 12:10:48

US3552497

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'Jan 2006'	System	28 Sep 2020 12:10:48

US3552497

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '2006'	System	28 Sep 2020 12:10:48

US3552497

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:35:00

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Cornification and dystrophic skin disorders, HLT: Skin dystrophies, PT: Keloid scar, LLT: Keloid - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 07:49:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 07:49:39
Data point term sent to Coder	System	28 Sep 2020 12:11:47
User entered 'keloid lesions on chest'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:11:29

US3552497

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2016'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:11:29

US3552497

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:35:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:11:29

US3552497

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:35:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:11:29

US3552497

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:11:29

US3552497

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:35:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:11:29

US3552497

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	28 Sep 2020 12:11:29

US3552497

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '2016'	System	28 Sep 2020 12:11:29

US3552497

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 12:11:29

US3552497

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 12:11:29

US3552497

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:12:02

US3552497

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:12:02

US3552497

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '13:09'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:12:02

US3552497

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '26 Sep 2020 13:09'	System	28 Sep 2020 12:12:02

US3552497

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '65' in	Stanley Dublin (b) (4)	28 Sep 2020 12:12:02
DataPoint set to visible.	(b) (4) System	26 Sep 2020 19:13:22

US3552497

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '195' lb	Stanley Dublin (b) (4)	28 Sep 2020 12:12:02
DataPoint set to visible.	(b) (4) System	26 Sep 2020 19:13:22

US3552497

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:00

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '32.51755'	System	28 Sep 2020 12:12:02
DataPoint set to visible.	System	26 Sep 2020 19:13:22

US3552497

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:00

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	28 Sep 2020 12:12:02
DataPoint set to visible.	System	26 Sep 2020 19:13:22

US3552497

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:00

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:12:02

US3552497

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:00

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:12:02

US3552497

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:00

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:12:02

US3552497

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:12:02

US3552497

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:00

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Sep 2020 12:12:02

US3552497

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:12:02

US3552497

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Sep 2020 12:12:02

US3552497

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:12:02

US3552497

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Sep 2020 12:12:02

US3552497

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:12:02

US3552497

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Sep 2020 12:12:02

US3552497

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:00

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:12:10

US3552497

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:00

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '26 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:12:10

US3552497

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '26 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:12:33

US3552497

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:12:33

US3552497

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:12:33

US3552497

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:12:33

US3552497

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:12:33

US3552497

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:35:00

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:12:33

US3552497

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:12:33

US3552497

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:35:00

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:12:33

US3552497

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:35:00

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:13:13

US3552497

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '26 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:13:13

US3552497

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:35:00

[Test performed](#)

Audit	User	Time (GMT)
User entered 'Urine (URINE)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:13:13

US3552497

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:35:00

[Result](#)

Audit	User	Time (GMT)
User entered 'Negative (NEGATIVE)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:13:13

US3552497

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:35:00

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:13:13

US3552497

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:35:00

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:13:13

US3552497

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:35:00

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:13:13

US3552497

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 12:13:13

US3552497

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:15

US3552497

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:15

US3552497

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:00

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)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:15

US3552497

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:15

US3552497

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:15

US3552497

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4)	28 Sep 2020 12:14:15
	(b) (4)	

US3552497

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:00

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)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:15

US3552497

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:00

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)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:15

US3552497

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:15

US3552497

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:00

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)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:14:15

US3552497

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:14:15

US3552497

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:00

Other

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:15

US3552497

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:00

[Specify](#)

Audit	User	Time (GMT)
User entered 'occupational therapy student, grocery shopping, nail salon, dine (outdoors)'	Stanley Dublin (b) (4)	28 Sep 2020 12:14:15

US3552497

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:00

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:15

US3552497

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:00

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:15

US3552497

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:00

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'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:14:15

US3552497

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '1'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:15

US3552497

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:00

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'	Stanley Dublin (b) (4)	28 Sep 2020 12:14:15
	(b) (4)	

US3552497

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:15

US3552497

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:00

Other

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:14:15

US3552497

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:00

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:15

US3552497

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:35:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:29

US3552497

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '26 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:29

US3552497

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:29

US3552497

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:35:00

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	28 Sep 2020 12:14:29

US3552497

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '26 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	26 Sep 2020 19:02:34

US3552497

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '115802'	RWS_ENDPOINT ENDPOINT (b) (4) 	26 Sep 2020 19:02:34

US3552497

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:00

[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 Sep 2020 19:02:34

US3552497

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:00

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)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:14:43

US3552497

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:14:43

US3552497

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:43

US3552497

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:43

US3552497

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:00

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:14:43

US3552497

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4)	28 Sep 2020 12:14:43
DataPoint set to visible.	(b) (4) System	26 Sep 2020 19:13:17

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:35:00

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:15:22

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:35:00

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:15:22

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:35:00

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:15:22

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:35:00

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:15:22

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:00

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:15:22

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:15:22

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:15:22

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '13:09'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:15:22

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '26 Sep 2020 13:09'	System	28 Sep 2020 12:15:22

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:00

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.8' F	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:15:22

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:00

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:15:22

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:00

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:15:22

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '68'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:15:22

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:00

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Sep 2020 12:15:22

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '16'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:15:22

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Sep 2020 12:15:22

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '109'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:15:22

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Sep 2020 12:15:22

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '77'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:15:22

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Sep 2020 12:15:22

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:35:00

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:15:22

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:35:00

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:15:22

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:00

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:15:59

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:15:59

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:15:59

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '14:55'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:15:59

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '26 Sep 2020 14:55'	System	28 Sep 2020 12:15:59

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:00

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.4' F	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:15:59

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:00

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:15:59

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:00

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:15:59

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '60'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:15:59

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:00

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Sep 2020 12:15:59

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '16'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:15:59

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Sep 2020 12:15:59

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '118'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:15:59

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Sep 2020 12:15:59

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '78'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:15:59

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Sep 2020 12:15:59

US3552497

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:00

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Stanley Dublin (b) (4)	28 Sep 2020 12:16:27
User entered 'Yes (Y)'	Stanley Dublin (b) (4)	28 Sep 2020 12:16:08

US3552497

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:00

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Stanley Dublin (b) (4)	28 Sep 2020 12:16:27
User entered '26 Sep 2020'	Stanley Dublin (b) (4)	28 Sep 2020 12:16:08

US3552497

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:35:00

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:16:16

US3552497

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:35:00

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:16:16

US3552497

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:35:00

[Test performed](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:16:16

US3552497

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:35:00

[Result](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:16:16

US3552497

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:35:00

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:16:16

US3552497

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:35:00

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:16:16

US3552497

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:35:00

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:16:16

US3552497

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 12:16:16

US3552497

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:00

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 19:32:56

US3552497

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:00

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 19:32:56

US3552497

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:00

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 Sep 2020 19:32:56

US3552497

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:00

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	26 Sep 2020 19:32:56

US3552497

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:00

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 19:32:56

US3552497

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '14:25'	(b) (4), (b) (6)	26 Sep 2020 19:32:56

US3552497

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '26 Sep 2020 14:25'	System	26 Sep 2020 19:32:56

US3552497

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	26 Sep 2020 19:32:56

US3552497

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	26 Sep 2020 19:32:56

US3552497

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	26 Sep 2020 19:32:56

US3552497

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:16:46

US3552497

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '26 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:16:46

US3552497

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '13:45'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:16:46

US3552497

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '26 Sep 2020 13:45'	System	28 Sep 2020 12:16:46

US3552497

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '26 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:16:58

US3552497

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:35:00

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stanley Dublin (b) (4)	28 Sep 2020 12:16:58

US3552497

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:35:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:16:58

US3552497

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '13:50'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:16:58

US3552497

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '26 Sep 2020 13:50'	System	28 Sep 2020 12:16:58

US3552497

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:35:00

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stanley Dublin (b) (4)	28 Sep 2020 12:16:58

US3552497

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:35:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:16:58

US3552497

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:16:58

US3552497

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 12:16:58

US3552497

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	05 Oct 2020 14:01:25

US3552497

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:35:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 14:01:25

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 19:32:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:35:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-26T14:53:49', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'bc85722b-3e13-48e2-b56e-746023aa767f'	System	26 Sep 2020 19:54:07
User entered 'Yes (Y)'	System	26 Sep 2020 19:54:07

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:35:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-26T14:53:55', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'bc85722b-3e13-48e2-b56e-746023aa767f'	System	26 Sep 2020 19:54:07
User entered '98.4'	System	26 Sep 2020 19:54:07

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-26T14:54:00', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'bc85722b-3e13-48e2-b56e-746023aa767f'	System	26 Sep 2020 19:54:07
User entered 'No (N)'	System	26 Sep 2020 19:54:07

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:35:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-26T14:54:03', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'bc85722b-3e13-48e2-b56e-746023aa767f'	System	26 Sep 2020 19:54:07
User entered '26 Sep 2020 14:54'	System	26 Sep 2020 19:54:07

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:35:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 14:45'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:35:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 17:15'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 19:32:56
User entered 'Day 1, after vaccination (at home)'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:35:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-26T19:31:19', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '2e860f9a-f604-43c2-a46f-4b8852b5cc87'	System	27 Sep 2020 00:31:33
User entered 'Yes (Y)'	System	27 Sep 2020 00:31:33

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:35:00

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-26T19:31:24', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '2e860f9a-f604-43c2-a46f-4b8852b5cc87'	System	27 Sep 2020 00:31:33
User entered '97.9'	System	27 Sep 2020 00:31:33

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-26T19:31:27', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '2e860f9a-f604-43c2-a46f-4b8852b5cc87'	System	27 Sep 2020 00:31:33
User entered 'No (N)'	System	27 Sep 2020 00:31:33

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:35:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-26T19:31:29', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '2e860f9a-f604-43c2-a46f-4b8852b5cc87'	System	27 Sep 2020 00:31:33
User entered '26 Sep 2020 19:31'	System	27 Sep 2020 00:31:33

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:35:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 18:10'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:35:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 19:32:56
User entered 'Day 2'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:35:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-27T13:09:41', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'e9eab12b-d340-4756-bf9c-4dec199ab952'	System	27 Sep 2020 18:09:51
User entered 'Yes (Y)'	System	27 Sep 2020 18:09:51

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:35:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-27T13:09:45', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'e9eab12b-d340-4756-bf9c-4dec199ab952'	System	27 Sep 2020 18:09:51
User entered '97.9'	System	27 Sep 2020 18:09:51

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-27T13:09:47', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'e9eab12b-d340-4756-bf9c-4dec199ab952'	System	27 Sep 2020 18:09:51
User entered 'No (N)'	System	27 Sep 2020 18:09:51

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:35:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-27T13:09:48', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'e9eab12b-d340-4756-bf9c-4dec199ab952'	System	27 Sep 2020 18:09:51
User entered '27 Sep 2020 13:09'	System	27 Sep 2020 18:09:51

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:35:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:35:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 19:32:56
User entered 'Day 3'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:35:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-28T17:57:50', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '6f02909c-4e6e-4e56-ae03-1e83edd9397d' User entered 'Yes (Y)'	System	28 Sep 2020 22:57:59
	System	28 Sep 2020 22:57:59

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:35:00

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-28T17:57:53', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '6f02909c-4e6e-4e56-ae03-1e83edd9397d' User entered '97.3'	System	28 Sep 2020 22:57:59

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:35:00

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-28T17:57:55', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '6f02909c-4e6e-4e56-ae03-1e83edd9397d'	System	28 Sep 2020 22:57:59
User entered 'No (N)'	System	28 Sep 2020 22:57:59

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:35:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-28T17:57:57', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '6f02909c-4e6e-4e56-ae03-1e83edd9397d' User entered '28 Sep 2020 17:57'	System	28 Sep 2020 22:57:59
	System	28 Sep 2020 22:57:59

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:35:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:35:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 19:32:56
User entered 'Day 4'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:35:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-29T13:56:12', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '2546f5f9-692f-49e0-8cd7-ed817b67434a'	System	29 Sep 2020 18:56:21
User entered 'Yes (Y)'	System	29 Sep 2020 18:56:21

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:35:00

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-29T13:56:16', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '2546f5f9-692f-49e0-8cd7-ed817b67434a' User entered '96.7'	System	29 Sep 2020 18:56:21
	System	29 Sep 2020 18:56:21

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-29T13:56:18', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '2546f5f9-692f-49e0-8cd7-ed817b67434a'	System	29 Sep 2020 18:56:21
User entered 'No (N)'	System	29 Sep 2020 18:56:21

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:35:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-29T13:56:19', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '2546f5f9-692f-49e0-8cd7-ed817b67434a' User entered '29 Sep 2020 13:56'	System	29 Sep 2020 18:56:21
	System	29 Sep 2020 18:56:21

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:35:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:35:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 19:32:56
User entered 'Day 5'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:35:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-30T22:43:35', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'c9fbde56-b4a6-4bb0-9108-ce99d8622ca9'	System	01 Oct 2020 03:43:42
User entered 'Yes (Y)'	System	01 Oct 2020 03:43:42

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:35:00

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-30T22:43:38', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'c9fbde56-b4a6-4bb0-9108-ce99d8622ca9'	System	01 Oct 2020 03:43:42
User entered '98.1'	System	01 Oct 2020 03:43:42

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-30T22:43:39', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'c9fbde56-b4a6-4bb0-9108-ce99d8622ca9'	System	01 Oct 2020 03:43:42
User entered 'No (N)'	System	01 Oct 2020 03:43:42

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:35:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-30T22:43:41', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'c9fbde56-b4a6-4bb0-9108-ce99d8622ca9'	System	01 Oct 2020 03:43:42
User entered '30 Sep 2020 22:43'	System	01 Oct 2020 03:43:42

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:35:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:35:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 19:32:56
User entered 'Day 6'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:35:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-10-02T00:04:41', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'b3f345c5-7bd5-4b57-9685-53d1cad17036'	System	02 Oct 2020 05:04:48
User entered 'Yes (Y)'	System	02 Oct 2020 05:04:48

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:35:00

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-10-02T00:04:43', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'b3f345c5-7bd5-4b57-9685-53d1cad17036'	System	02 Oct 2020 05:04:48
User entered '98.1'	System	02 Oct 2020 05:04:48

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-10-02T00:04:45', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'b3f345c5-7bd5-4b57-9685-53d1cad17036'	System	02 Oct 2020 05:04:48
User entered 'No (N)'	System	02 Oct 2020 05:04:48

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:35:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-10-02T00:04:47', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'b3f345c5-7bd5-4b57-9685-53d1cad17036' User entered '02 Oct 2020 00:04'	System	02 Oct 2020 05:04:48
	System	02 Oct 2020 05:04:48

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:35:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:35:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 19:32:56
User entered 'Day 7'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:35:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-10-02T21:57:23', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '8bb02bf4-2195-4b34-af2f-49bbffd7ad96'	System	03 Oct 2020 02:57:33
User entered 'Yes (Y)'	System	03 Oct 2020 02:57:33

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:35:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-10-02T21:57:27', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '8bb02bf4-2195-4b34-af2f-49bbffd7ad96'	System	03 Oct 2020 02:57:33
User entered '98.3'	System	03 Oct 2020 02:57:33

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-10-02T21:57:29', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '8bb02bf4-2195-4b34-af2f-49bbffd7ad96'	System	03 Oct 2020 02:57:33
User entered 'No (N)'	System	03 Oct 2020 02:57:33

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:35:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-10-02T21:57:31', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '8bb02bf4-2195-4b34-af2f-49bbffd7ad96'	System	03 Oct 2020 02:57:33
User entered '02 Oct 2020 21:57'	System	03 Oct 2020 02:57:33

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:35:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:35:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 19:32:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:35:00

[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 (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-26T14:54:37', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'c5036619-a49b-43b1-9574-88cbe1277d97'	System	26 Sep 2020 19:55:03
User entered 'None (1)'	System	26 Sep 2020 19:55:03

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-26T14:54:39', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'c5036619-a49b-43b1-9574-88cbe1277d97'	System	26 Sep 2020 19:55:03
User entered 'No (N)'	System	26 Sep 2020 19:55:03

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-26T14:54:43', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'c5036619-a49b-43b1-9574-88cbe1277d97'	System	26 Sep 2020 19:55:03
User entered 'No (N)'	System	26 Sep 2020 19:55:03

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:35:00

[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 (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-26T14:54:57', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'c5036619-a49b-43b1-9574-88cbe1277d97'	System	26 Sep 2020 19:55:03
User entered 'None (1)'	System	26 Sep 2020 19:55:03

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:35:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-26T14:54:59', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'c5036619-a49b-43b1-9574-88cbe1277d97'	System	26 Sep 2020 19:55:03
User entered '26 Sep 2020 14:54'	System	26 Sep 2020 19:55:03

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:35:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 14:45'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:35:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 17:15'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 19:32:56
User entered 'Day 1, after vaccination (at home)'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:35:00

[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 (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-26T19:30:07', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '6fc12370-6d29-4989-bbf9-ebb47da9974c'	System	27 Sep 2020 00:31:15
User entered 'Does not interfere with activity (2)'	System	27 Sep 2020 00:31:15

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-26T19:30:14', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '6fc12370-6d29-4989-bbf9-ebb47da9974c'	System	27 Sep 2020 00:31:15
User entered 'No (N)'	System	27 Sep 2020 00:31:15

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-26T19:30:16', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '6fc12370-6d29-4989-bbf9-ebb47da9974c'	System	27 Sep 2020 00:31:15
User entered 'Yes (Y)'	System	27 Sep 2020 00:31:15

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:35:00

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-26T19:30:54', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '6fc12370-6d29-4989-bbf9-ebb47da9974c' User entered '5'	System	27 Sep 2020 00:31:15
	System	27 Sep 2020 00:31:15

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:35:00

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 (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-26T19:31:07', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '6fc12370-6d29-4989-bbf9-ebb47da9974c'	System	27 Sep 2020 00:31:15
User entered 'None (1)'	System	27 Sep 2020 00:31:15

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:35:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-26T19:31:10', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '6fc12370-6d29-4989-bbf9-ebb47da9974c'	System	27 Sep 2020 00:31:15
User entered '26 Sep 2020 19:31'	System	27 Sep 2020 00:31:15

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:35:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 18:10'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:35:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 19:32:56
User entered 'Day 2'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:35:00

[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 (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-27T13:10:09', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'a57d8683-d31d-4cb1-8b46-d43db9afab64'	System	27 Sep 2020 18:10:54
User entered 'Does not interfere with activity (2)'	System	27 Sep 2020 18:10:54

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-27T13:10:11', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'a57d8683-d31d-4cb1-8b46-d43db9afab64'	System	27 Sep 2020 18:10:54
User entered 'No (N)'	System	27 Sep 2020 18:10:54

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-27T13:10:25', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'a57d8683-d31d-4cb1-8b46-d43db9afab64'	System	27 Sep 2020 18:10:54
User entered 'No (N)'	System	27 Sep 2020 18:10:54

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:35:00

[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 (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-27T13:10:48', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'a57d8683-d31d-4cb1-8b46-d43db9afab64'	System	27 Sep 2020 18:10:54
User entered 'None (1)'	System	27 Sep 2020 18:10:54

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:35:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-27T13:10:49', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'a57d8683-d31d-4cb1-8b46-d43db9afab64'	System	27 Sep 2020 18:10:54
User entered '27 Sep 2020 13:10'	System	27 Sep 2020 18:10:54

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:35:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:35:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 19:32:56
User entered 'Day 3'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:35:00

[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 (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-28T17:58:04', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'd0049ca0-3615-4fd3-8632-97e023b0c278'	System	28 Sep 2020 22:58:13
User entered 'Does not interfere with activity (2)'	System	28 Sep 2020 22:58:13

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-28T17:58:05', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'd0049ca0-3615-4fd3-8632-97e023b0c278'	System	28 Sep 2020 22:58:13
User entered 'No (N)'	System	28 Sep 2020 22:58:13

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-28T17:58:07', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'd0049ca0-3615-4fd3-8632-97e023b0c278'	System	28 Sep 2020 22:58:13
User entered 'No (N)'	System	28 Sep 2020 22:58:13

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:35:00

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 (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-28T17:58:09', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'd0049ca0-3615-4fd3-8632-97e023b0c278'	System	28 Sep 2020 22:58:13
User entered 'None (1)'	System	28 Sep 2020 22:58:13

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:35:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-28T17:58:10', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'd0049ca0-3615-4fd3-8632-97e023b0c278'	System	28 Sep 2020 22:58:13
User entered '28 Sep 2020 17:58'	System	28 Sep 2020 22:58:13

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:35:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:35:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 19:32:56
User entered 'Day 4'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:35:00

[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 (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-29T13:56:24', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'a990c9fb-34c2-47f0-9677-cca2b7760c41'	System	29 Sep 2020 18:56:36
User entered 'None (1)'	System	29 Sep 2020 18:56:36

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-29T13:56:26', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'a990c9fb-34c2-47f0-9677-cca2b7760c41'	System	29 Sep 2020 18:56:36
User entered 'No (N)'	System	29 Sep 2020 18:56:36

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-29T13:56:27', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'a990c9fb-34c2-47f0-9677-cca2b7760c41'	System	29 Sep 2020 18:56:36
User entered 'No (N)'	System	29 Sep 2020 18:56:36

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:35:00

[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 (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-29T13:56:30', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'a990c9fb-34c2-47f0-9677-cca2b7760c41'	System	29 Sep 2020 18:56:36
User entered 'None (1)'	System	29 Sep 2020 18:56:36

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:35:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-29T13:56:32', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'a990c9fb-34c2-47f0-9677-cca2b7760c41'	System	29 Sep 2020 18:56:36
User entered '29 Sep 2020 13:56'	System	29 Sep 2020 18:56:36

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:35:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:35:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 19:32:56
User entered 'Day 5'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:35:00

[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 (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-30T22:43:44', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '436ce5a2-6188-4923-9c36-635ba156d905'	System	01 Oct 2020 03:43:54
User entered 'None (1)'	System	01 Oct 2020 03:43:54

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-30T22:43:45', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '436ce5a2-6188-4923-9c36-635ba156d905'	System	01 Oct 2020 03:43:54
User entered 'No (N)'	System	01 Oct 2020 03:43:54

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-30T22:43:47', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '436ce5a2-6188-4923-9c36-635ba156d905'	System	01 Oct 2020 03:43:54
User entered 'No (N)'	System	01 Oct 2020 03:43:54

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:35:00

[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 (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-30T22:43:48', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '436ce5a2-6188-4923-9c36-635ba156d905'	System	01 Oct 2020 03:43:54
User entered 'None (1)'	System	01 Oct 2020 03:43:54

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:35:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-30T22:43:49', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '436ce5a2-6188-4923-9c36-635ba156d905'	System	01 Oct 2020 03:43:54
User entered '30 Sep 2020 22:43'	System	01 Oct 2020 03:43:54

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:35:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:35:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 19:32:56
User entered 'Day 6'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:35:00

[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 (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-10-02T00:04:49', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'a559cc0d-e61e-48ae-8641-2d12109460b3'	System	02 Oct 2020 05:04:56
User entered 'None (1)'	System	02 Oct 2020 05:04:56

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-10-02T00:04:50', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'a559cc0d-e61e-48ae-8641-2d12109460b3'	System	02 Oct 2020 05:04:56
User entered 'No (N)'	System	02 Oct 2020 05:04:56

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-10-02T00:04:51', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'a559cc0d-e61e-48ae-8641-2d12109460b3' User entered 'No (N)'	System	02 Oct 2020 05:04:56
	System	02 Oct 2020 05:04:56

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:35:00

[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 (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-10-02T00:04:53', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'a559cc0d-e61e-48ae-8641-2d12109460b3'	System	02 Oct 2020 05:04:56
User entered 'None (1)'	System	02 Oct 2020 05:04:56

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:35:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-10-02T00:04:54', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'a559cc0d-e61e-48ae-8641-2d12109460b3'	System	02 Oct 2020 05:04:56
User entered '02 Oct 2020 00:04'	System	02 Oct 2020 05:04:56

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:35:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:35:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 19:32:56
User entered 'Day 7'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:35:00

[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 (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-10-02T21:57:34', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '21177b24-63af-4d9d-b28b-c8fae82a14d8'	System	03 Oct 2020 02:57:43
User entered 'None (1)'	System	03 Oct 2020 02:57:43

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-10-02T21:57:36', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '21177b24-63af-4d9d-b28b-c8fae82a14d8'	System	03 Oct 2020 02:57:43
User entered 'No (N)'	System	03 Oct 2020 02:57:43

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-10-02T21:57:37', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '21177b24-63af-4d9d-b28b-c8fae82a14d8'	System	03 Oct 2020 02:57:43
User entered 'No (N)'	System	03 Oct 2020 02:57:43

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:35:00

[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 (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-10-02T21:57:38', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '21177b24-63af-4d9d-b28b-c8fae82a14d8'	System	03 Oct 2020 02:57:43
User entered 'None (1)'	System	03 Oct 2020 02:57:43

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:35:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-10-02T21:57:40', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '21177b24-63af-4d9d-b28b-c8fae82a14d8'	System	03 Oct 2020 02:57:43
User entered '02 Oct 2020 21:57'	System	03 Oct 2020 02:57:43

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:35:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:35:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 19:32:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:35:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-26T14:55:05', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'ba9a2061-3758-47f9-9d5c-45b256b00d6e'	System	26 Sep 2020 19:55:42
User entered 'None (0)'	System	26 Sep 2020 19:55:42

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:35:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-26T14:55:16', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'ba9a2061-3758-47f9-9d5c-45b256b00d6e' User entered 'None (0)'	System	26 Sep 2020 19:55:42
	System	26 Sep 2020 19:55:42

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:35:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-26T14:55:19', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'ba9a2061-3758-47f9-9d5c-45b256b00d6e' User entered 'None (0)'	System	26 Sep 2020 19:55:42
	System	26 Sep 2020 19:55:42

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:35:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-26T14:55:25', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'ba9a2061-3758-47f9-9d5c-45b256b00d6e' User entered 'None (0)'	System	26 Sep 2020 19:55:42
	System	26 Sep 2020 19:55:42

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:35:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-26T14:55:27', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'ba9a2061-3758-47f9-9d5c-45b256b00d6e' User entered 'None (0)'	System	26 Sep 2020 19:55:42
	System	26 Sep 2020 19:55:42

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:35:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-26T14:55:28', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'ba9a2061-3758-47f9-9d5c-45b256b00d6e' User entered 'None (0)'	System	26 Sep 2020 19:55:42
	System	26 Sep 2020 19:55:42

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:35:00

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 (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-26T14:55:38', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'ba9a2061-3758-47f9-9d5c-45b256b00d6e'	System	26 Sep 2020 19:55:42
User entered 'No (N)'	System	26 Sep 2020 19:55:42

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:35:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-26T14:55:41', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'ba9a2061-3758-47f9-9d5c-45b256b00d6e' User entered '26 Sep 2020 14:55'	System	26 Sep 2020 19:55:42
	System	26 Sep 2020 19:55:42

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:35:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 14:45'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:35:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 17:15'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 19:32:56
User entered 'Day 1, after vaccination (at home)'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:35:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-26T19:31:38', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'ed4f762c-bf91-48ba-878e-fd77d5c17a5a'	System	27 Sep 2020 00:31:59
User entered 'None (0)'	System	27 Sep 2020 00:31:59

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:35:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-26T19:31:40', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'ed4f762c-bf91-48ba-878e-fd77d5c17a5a'	System	27 Sep 2020 00:31:59
User entered 'None (0)'	System	27 Sep 2020 00:31:59

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:35:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-26T19:31:43', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'ed4f762c-bf91-48ba-878e-fd77d5c17a5a'	System	27 Sep 2020 00:31:59
User entered 'None (0)'	System	27 Sep 2020 00:31:59

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:35:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-26T19:31:44', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'ed4f762c-bf91-48ba-878e-fd77d5c17a5a'	System	27 Sep 2020 00:31:59
User entered 'None (0)'	System	27 Sep 2020 00:31:59

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:35:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-26T19:31:46', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'ed4f762c-bf91-48ba-878e-fd77d5c17a5a'	System	27 Sep 2020 00:31:59
User entered 'None (0)'	System	27 Sep 2020 00:31:59

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:35:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-26T19:31:47', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'ed4f762c-bf91-48ba-878e-fd77d5c17a5a'	System	27 Sep 2020 00:31:59
User entered 'None (0)'	System	27 Sep 2020 00:31:59

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:35:00

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 (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-26T19:31:52', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'ed4f762c-bf91-48ba-878e-fd77d5c17a5a'	System	27 Sep 2020 00:31:59
User entered 'No (N)'	System	27 Sep 2020 00:31:59

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:35:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-26T19:31:54', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'ed4f762c-bf91-48ba-878e-fd77d5c17a5a'	System	27 Sep 2020 00:31:59
User entered '26 Sep 2020 19:31'	System	27 Sep 2020 00:31:59

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:35:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 18:10'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:35:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 19:32:56
User entered 'Day 2'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:35:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-27T13:10:53', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'a3c955b7-a99a-4c0c-ae22-e1fd6cef07f1'	System	27 Sep 2020 18:11:10
User entered 'None (0)'	System	27 Sep 2020 18:11:10

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:35:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-27T13:10:55', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'a3c955b7-a99a-4c0c-ae22-e1fd6cef07f1'	System	27 Sep 2020 18:11:10
User entered 'None (0)'	System	27 Sep 2020 18:11:10

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:35:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-27T13:10:57', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'a3c955b7-a99a-4c0c-ae22-e1fd6cef07f1'	System	27 Sep 2020 18:11:10
User entered 'None (0)'	System	27 Sep 2020 18:11:10

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:35:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-27T13:10:58', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'a3c955b7-a99a-4c0c-ae22-e1fd6cef07f1'	System	27 Sep 2020 18:11:10
User entered 'None (0)'	System	27 Sep 2020 18:11:10

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:35:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-27T13:10:59', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'a3c955b7-a99a-4c0c-ae22-e1fd6cef07f1'	System	27 Sep 2020 18:11:10
User entered 'None (0)'	System	27 Sep 2020 18:11:10

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:35:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-27T13:11:00', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'a3c955b7-a99a-4c0c-ae22-e1fd6cef07f1'	System	27 Sep 2020 18:11:10
User entered 'None (0)'	System	27 Sep 2020 18:11:10

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:35:00

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 (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-27T13:11:03', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'a3c955b7-a99a-4c0c-ae22-e1fd6cef07f1'	System	27 Sep 2020 18:11:10
User entered 'No (N)'	System	27 Sep 2020 18:11:10

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:35:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-27T13:11:05', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'a3c955b7-a99a-4c0c-ae22-e1fd6cef07f1'	System	27 Sep 2020 18:11:10
User entered '27 Sep 2020 13:11'	System	27 Sep 2020 18:11:10

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:35:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:35:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 19:32:56
User entered 'Day 3'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:35:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-28T17:58:15', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'e44b270c-25a3-4f76-b6cd-88684c7fc090'	System	28 Sep 2020 22:58:32
User entered 'None (0)'	System	28 Sep 2020 22:58:32

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:35:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-28T17:58:19', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'e44b270c-25a3-4f76-b6cd-88684c7fc090'	System	28 Sep 2020 22:58:32
User entered 'No interference with activity (1)'	System	28 Sep 2020 22:58:32

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:35:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-28T17:58:20', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'e44b270c-25a3-4f76-b6cd-88684c7fc090'	System	28 Sep 2020 22:58:32
User entered 'None (0)'	System	28 Sep 2020 22:58:32

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:35:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-28T17:58:21', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'e44b270c-25a3-4f76-b6cd-88684c7fc090'	System	28 Sep 2020 22:58:32
User entered 'None (0)'	System	28 Sep 2020 22:58:32

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:35:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-28T17:58:22', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'e44b270c-25a3-4f76-b6cd-88684c7fc090'	System	28 Sep 2020 22:58:32
User entered 'None (0)'	System	28 Sep 2020 22:58:32

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:35:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-28T17:58:23', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'e44b270c-25a3-4f76-b6cd-88684c7fc090'	System	28 Sep 2020 22:58:32
User entered 'None (0)'	System	28 Sep 2020 22:58:32

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:35:00

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 (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-28T17:58:25', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'e44b270c-25a3-4f76-b6cd-88684c7fc090'	System	28 Sep 2020 22:58:32
User entered 'No (N)'	System	28 Sep 2020 22:58:32

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:35:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-28T17:58:27', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'e44b270c-25a3-4f76-b6cd-88684c7fc090'	System	28 Sep 2020 22:58:32
User entered '28 Sep 2020 17:58'	System	28 Sep 2020 22:58:32

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:35:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:35:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 19:32:56
User entered 'Day 4'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:35:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-29T13:56:34', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'bcd717f2-9008-4bb6-9c15-46740802255e'	System	29 Sep 2020 18:56:47
User entered 'None (0)'	System	29 Sep 2020 18:56:47

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:35:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-29T13:56:35', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'bcd717f2-9008-4bb6-9c15-46740802255e' User entered 'None (0)'	System	29 Sep 2020 18:56:47
	System	29 Sep 2020 18:56:47

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:35:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-29T13:56:36', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'bcd717f2-9008-4bb6-9c15-46740802255e'	System	29 Sep 2020 18:56:47
User entered 'None (0)'	System	29 Sep 2020 18:56:47

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:35:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-29T13:56:37', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'bcd717f2-9008-4bb6-9c15-46740802255e' User entered 'None (0)'	System	29 Sep 2020 18:56:47
	System	29 Sep 2020 18:56:47

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:35:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-29T13:56:38', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'bcd717f2-9008-4bb6-9c15-46740802255e' User entered 'None (0)'	System	29 Sep 2020 18:56:47
	System	29 Sep 2020 18:56:47

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:35:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-29T13:56:39', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'bcd717f2-9008-4bb6-9c15-46740802255e'	System	29 Sep 2020 18:56:47
User entered 'None (0)'	System	29 Sep 2020 18:56:47

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:35:00

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 (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-29T13:56:41', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'bcd717f2-9008-4bb6-9c15-46740802255e'	System	29 Sep 2020 18:56:47
User entered 'No (N)'	System	29 Sep 2020 18:56:47

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:35:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-29T13:56:42', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'bcd717f2-9008-4bb6-9c15-46740802255e' User entered '29 Sep 2020 13:56'	System	29 Sep 2020 18:56:47
	System	29 Sep 2020 18:56:47

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:35:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:35:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 19:32:56
User entered 'Day 5'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:35:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-30T22:43:51', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '9154c443-af43-4213-82c0-0239d130315f' User entered 'None (0)'	System	01 Oct 2020 03:44:02
	System	01 Oct 2020 03:44:02

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:35:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-30T22:43:52', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '9154c443-af43-4213-82c0-0239d130315f' User entered 'None (0)'	System	01 Oct 2020 03:44:02
	System	01 Oct 2020 03:44:02

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:35:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-30T22:43:53', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '9154c443-af43-4213-82c0-0239d130315f' User entered 'None (0)'	System	01 Oct 2020 03:44:02
	System	01 Oct 2020 03:44:02

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:35:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-30T22:43:55', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '9154c443-af43-4213-82c0-0239d130315f' User entered 'None (0)'	System	01 Oct 2020 03:44:02
	System	01 Oct 2020 03:44:02

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:35:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-30T22:43:56', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '9154c443-af43-4213-82c0-0239d130315f'	System	01 Oct 2020 03:44:02
User entered 'None (0)'	System	01 Oct 2020 03:44:02

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:35:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-30T22:43:57', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '9154c443-af43-4213-82c0-0239d130315f' User entered 'None (0)'	System	01 Oct 2020 03:44:02
	System	01 Oct 2020 03:44:02

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:35:00

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 (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-30T22:43:58', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '9154c443-af43-4213-82c0-0239d130315f'	System	01 Oct 2020 03:44:02
User entered 'No (N)'	System	01 Oct 2020 03:44:02

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:35:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-09-30T22:44:00', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '9154c443-af43-4213-82c0-0239d130315f' User entered '30 Sep 2020 22:44'	System	01 Oct 2020 03:44:02
	System	01 Oct 2020 03:44:02

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:35:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:35:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 19:32:56
User entered 'Day 6'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:35:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-10-02T00:04:56', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '17bb4b39-c4d9-44d5-988e-fab6123208ee' User entered 'None (0)'	System	02 Oct 2020 05:05:07
	System	02 Oct 2020 05:05:07

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:35:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-10-02T00:04:57', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '17bb4b39-c4d9-44d5-988e-fab6123208ee' User entered 'None (0)'	System	02 Oct 2020 05:05:07
	System	02 Oct 2020 05:05:07

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:35:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-10-02T00:04:58', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '17bb4b39-c4d9-44d5-988e-fab6123208ee' User entered 'None (0)'	System	02 Oct 2020 05:05:07
	System	02 Oct 2020 05:05:07

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:35:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-10-02T00:05:00', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '17bb4b39-c4d9-44d5-988e-fab6123208ee' User entered 'None (0)'	System	02 Oct 2020 05:05:07
	System	02 Oct 2020 05:05:07

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:35:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-10-02T00:05:01', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '17bb4b39-c4d9-44d5-988e-fab6123208ee' User entered 'None (0)'	System	02 Oct 2020 05:05:07
	System	02 Oct 2020 05:05:07

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:35:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-10-02T00:05:02', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '17bb4b39-c4d9-44d5-988e-fab6123208ee' User entered 'None (0)'	System	02 Oct 2020 05:05:07
	System	02 Oct 2020 05:05:07

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:35:00

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 (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-10-02T00:05:04', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '17bb4b39-c4d9-44d5-988e-fab6123208ee' User entered 'No (N)'	System	02 Oct 2020 05:05:07

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:35:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-10-02T00:05:06', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '17bb4b39-c4d9-44d5-988e-fab6123208ee' User entered '02 Oct 2020 00:05'	System	02 Oct 2020 05:05:07
	System	02 Oct 2020 05:05:07

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:35:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:35:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 19:32:56
User entered 'Day 7'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:35:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-10-02T21:57:43', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'cfeb745a-5c88-48a7-b8e3-3bb599616e0f'	System	03 Oct 2020 02:57:57
User entered 'None (0)'	System	03 Oct 2020 02:57:57

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:35:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-10-02T21:57:45', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'cfeb745a-5c88-48a7-b8e3-3bb599616e0f' User entered 'None (0)'	System	03 Oct 2020 02:57:57

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:35:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-10-02T21:57:47', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'cfeb745a-5c88-48a7-b8e3-3bb599616e0f' User entered 'None (0)'	System	03 Oct 2020 02:57:57

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:35:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-10-02T21:57:48', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'cfeb745a-5c88-48a7-b8e3-3bb599616e0f' User entered 'None (0)'	System	03 Oct 2020 02:57:57

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:35:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-10-02T21:57:50', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'cfeb745a-5c88-48a7-b8e3-3bb599616e0f'	System	03 Oct 2020 02:57:57
User entered 'None (0)'	System	03 Oct 2020 02:57:57

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:35:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-10-02T21:57:51', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'cfeb745a-5c88-48a7-b8e3-3bb599616e0f'	System	03 Oct 2020 02:57:57
User entered 'None (0)'	System	03 Oct 2020 02:57:57

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:35:00

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 (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-10-02T21:57:53', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'cfeb745a-5c88-48a7-b8e3-3bb599616e0f'	System	03 Oct 2020 02:57:57
User entered 'No (N)'	System	03 Oct 2020 02:57:57

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:35:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-10-02T21:57:56', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'cfeb745a-5c88-48a7-b8e3-3bb599616e0f'	System	03 Oct 2020 02:57:57
User entered '02 Oct 2020 21:57'	System	03 Oct 2020 02:57:57

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:35:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	26 Sep 2020 19:32:56

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:35:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	26 Sep 2020 19:32:56

US3552497

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	05 Oct 2020 14:01:35

US3552497

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:00

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020' reason for change: Data Entry Error	Heather Douds (b) (4)	09 Nov 2020 18:32:16
User entered '5 Oct 2020'	Stanley Dublin (b) (4)	05 Oct 2020 14:01:35

US3552497

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	05 Oct 2020 14:01:35

US3552497

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	05 Oct 2020 14:01:35

US3552497

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	13 Oct 2020 12:30:12

US3552497

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 12:30:12

US3552497

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 12:30:21

US3552497

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:00

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	13 Oct 2020 12:30:21

US3552497

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	13 Oct 2020 12:30:21

US3552497

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 12:30:21

US3552497

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 17:10:18

US3552497

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 17:10:18

US3552497

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 17:10:26

US3552497

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:00

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 17:10:26

US3552497

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4)	19 Oct 2020 17:10:26

US3552497

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 17:10:26

US3552497

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 21:04:56

US3552497

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 21:04:56

US3552497

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:57:27

US3552497

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '29 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:57:27

US3552497

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:57:27

US3552497

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:00

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	30 Oct 2020 15:57:27

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:00

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '15:30'	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '29 Oct 2020 15:30'	System	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:00

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '99.0' F	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:00

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:00

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '83'	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:00

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '22'	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '129'	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '80'	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:00

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:00

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:00

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:00

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:00

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:00

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:14

US3552497

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:00

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '29 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:14

US3552497

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:35:00

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:26

US3552497

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '29 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:26

US3552497

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:35:00

[Test performed](#)

Audit	User	Time (GMT)
User entered 'Urine (URINE)'	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:26

US3552497

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:35:00

[Result](#)

Audit	User	Time (GMT)
User entered 'Negative (NEGATIVE)'	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:26

US3552497

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:35:00

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:26

US3552497

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:35:00

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:26

US3552497

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:35:00

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:26

US3552497

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 15:59:26

US3552497

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:35:00

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 16:00:06

US3552497

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:35:00

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered 'Physician Decision (PHYSICIAN DECISION)'	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 16:00:06

US3552497

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User closed query 'Please update the entry to specify AE - RASH TO LEFT ARM' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 17:14:09
Query 'Please update the entry to specify AE - RASH TO LEFT ARM' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4)	18 Nov 2020 16:19:36
User entered 'RASH TO LEFT ARM' reason for change: Per Query Resolution	(b) (4)	18 Nov 2020 16:19:32
User opened query 'Please update the entry to specify AE - RASH TO LEFT ARM' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 02:40:44
User closed query 'Per CDM: Please update the reason why Study treatment was not given.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 06:28:48
Query 'Per CDM: Please update the reason why Study treatment was not given.' answered with 'updated' (Site from DM).	Heather Douds (b) (4)	10 Nov 2020 17:00:14
User entered 'AE #1' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 17:00:08
User opened query 'Per CDM: Please update the reason why Study treatment was not given.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 09:31:39
User entered empty.	Mikayla Frye (b) (4)	30 Oct 2020 16:00:06

US3552497

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:35:00

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 16:00:06

US3552497

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:35:00

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 16:00:06

US3552497

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 16:00:06

US3552497

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 16:00:06

US3552497

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 16:00:06

US3552497

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 16:00:06

US3552497

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 16:00:06

US3552497

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 16:00:20

US3552497

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:00

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 16:00:20

US3552497

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '15:47'	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 16:00:20

US3552497

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '29 Oct 2020 15:47'	System	30 Oct 2020 16:00:20

US3552497

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '29 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 16:00:34

US3552497

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:35:00

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 16:00:34

US3552497

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:35:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 16:00:34

US3552497

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '16:12'	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 16:00:34

US3552497

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '29 Oct 2020 16:12'	System	30 Oct 2020 16:00:34

US3552497

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:35:00

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 16:00:34

US3552497

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:35:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 16:00:34

US3552497

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 16:00:34

US3552497

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 16:00:34

US3552497

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	05 Nov 2020 16:48:15

US3552497

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 16:48:15

US3552497

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	05 Nov 2020 16:48:25

US3552497

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:00

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '05 Nov 2020' reason for change: Data Entry Error	Heather Douds (b) (4)	09 Nov 2020 18:32:24
User entered '5 Nov 2020'	Stanley Dublin (b) (4)	05 Nov 2020 16:48:25

US3552497

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4)	05 Nov 2020 16:48:25

US3552497

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	05 Nov 2020 16:48:25

US3552497

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	12 Nov 2020 22:15:07

US3552497

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 22:15:07

US3552497

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	12 Nov 2020 22:15:16

US3552497

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:00

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '12 Nov 2020'	Mikayla Frye (b) (4) (b) (4)	12 Nov 2020 22:15:16

US3552497

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Mikayla Frye (b) (4) (b) (4)	12 Nov 2020 22:15:16

US3552497

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	12 Nov 2020 22:15:16

US3552497

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	19 Nov 2020 20:23:06

US3552497

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 20:23:06

US3552497

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	19 Nov 2020 20:23:14

US3552497

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:00

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '19 Nov 2020'	Mikayla Frye (b) (4) (b) (4)	19 Nov 2020 20:23:14

US3552497

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Mikayla Frye (b) (4) (b) (4)	19 Nov 2020 20:23:14

US3552497

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	19 Nov 2020 20:23:14

US3552497

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	20 Nov 2020 16:06:50

US3552497

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 16:06:50

US3552497

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	20 Nov 2020 16:07:00

US3552497

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '20 Nov 2020'	Stanley Dublin (b) (4) (b) (4)	20 Nov 2020 16:07:00

US3552497

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Stanley Doublin (b) (4) (b) (4)	20 Nov 2020 16:07:00

US3552497

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:00

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	20 Nov 2020 16:07:00

US3552497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	20 Nov 2020 16:07:05

US3552497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	20 Nov 2020 16:07:05

US3552497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	20 Nov 2020 16:07:05

US3552497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 16:07:05

US3552497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:00

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	20 Nov 2020 16:07:05

US3552497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:00

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	20 Nov 2020 16:07:05

US3552497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:00

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	20 Nov 2020 16:07:05

US3552497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	20 Nov 2020 16:07:05

US3552497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:00

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 16:07:05

US3552497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	20 Nov 2020 16:07:05

US3552497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 16:07:05

US3552497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	20 Nov 2020 16:07:05

US3552497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 16:07:05

US3552497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	20 Nov 2020 16:07:05

US3552497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 16:07:05

US3552497

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:00

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	20 Nov 2020 16:07:11

US3552497

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:00

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	20 Nov 2020 16:07:11

US3552497

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	20 Nov 2020 16:07:23

US3552497

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '20 Nov 2020'	Stanley Dublin (b) (4) (b) (4)	20 Nov 2020 16:07:23

US3552497

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '08:42'	Stanley Dublin (b) (4) (b) (4)	20 Nov 2020 16:07:23

US3552497

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '20 Nov 2020 08:42'	System	20 Nov 2020 16:07:23

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '23 Nov 2020 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '27 Nov 2020 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '30 Nov 2020 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '04 Dec 2020 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '07 Dec 2020 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '11 Dec 2020 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '14 Dec 2020 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '18 Dec 2020 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '21 Dec 2020 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '25 Dec 2020 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '28 Dec 2020 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '01 Jan 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '04 Jan 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '08 Jan 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '11 Jan 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '15 Jan 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '18 Jan 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '22 Jan 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '25 Jan 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '29 Jan 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '01 Feb 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '05 Feb 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '08 Feb 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '12 Feb 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '15 Feb 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '19 Feb 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '22 Feb 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '26 Feb 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '01 Mar 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '05 Mar 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '08 Mar 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '12 Mar 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '15 Mar 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '19 Mar 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '22 Mar 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '26 Mar 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '29 Mar 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '02 Apr 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '05 Apr 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '09 Apr 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '12 Apr 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '16 Apr 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '19 Apr 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '23 Apr 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '26 Apr 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '30 Apr 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '03 May 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '07 May 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '10 May 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '14 May 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '17 May 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '21 May 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '24 May 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '28 May 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '31 May 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '04 Jun 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '07 Jun 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '11 Jun 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '14 Jun 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '18 Jun 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '21 Jun 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '25 Jun 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '28 Jun 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '02 Jul 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '05 Jul 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '09 Jul 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '12 Jul 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '16 Jul 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '19 Jul 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '23 Jul 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '26 Jul 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '30 Jul 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '02 Aug 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '06 Aug 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '09 Aug 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '13 Aug 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '16 Aug 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '20 Aug 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '23 Aug 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '27 Aug 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '30 Aug 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '03 Sep 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '06 Sep 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '10 Sep 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '13 Sep 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '17 Sep 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '20 Sep 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '24 Sep 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '27 Sep 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '01 Oct 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '04 Oct 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '08 Oct 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '11 Oct 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '15 Oct 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '18 Oct 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '22 Oct 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '25 Oct 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '29 Oct 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '01 Nov 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '05 Nov 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '08 Nov 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '12 Nov 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '15 Nov 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '19 Nov 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '22 Nov 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '26 Nov 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '29 Nov 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '03 Dec 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '06 Dec 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '10 Dec 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '13 Dec 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '17 Dec 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '20 Dec 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '24 Dec 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '27 Dec 2021 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '31 Dec 2021 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '03 Jan 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '07 Jan 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '10 Jan 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '14 Jan 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '17 Jan 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '21 Jan 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '24 Jan 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '28 Jan 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '31 Jan 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '04 Feb 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '07 Feb 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '11 Feb 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '14 Feb 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '18 Feb 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '21 Feb 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '25 Feb 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '28 Feb 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '04 Mar 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '07 Mar 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '11 Mar 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '14 Mar 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '18 Mar 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '21 Mar 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '25 Mar 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '28 Mar 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '01 Apr 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '04 Apr 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '08 Apr 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '11 Apr 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '15 Apr 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '18 Apr 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '22 Apr 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '25 Apr 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '29 Apr 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '02 May 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '06 May 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '09 May 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '13 May 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '16 May 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '20 May 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '23 May 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '27 May 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '30 May 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '03 Jun 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '06 Jun 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '10 Jun 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '13 Jun 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '17 Jun 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '20 Jun 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '24 Jun 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '27 Jun 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '01 Jul 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '04 Jul 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '08 Jul 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '11 Jul 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '15 Jul 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '18 Jul 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '22 Jul 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '25 Jul 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '29 Jul 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '01 Aug 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '05 Aug 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '08 Aug 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '12 Aug 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '15 Aug 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '19 Aug 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '22 Aug 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '26 Aug 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '29 Aug 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '02 Sep 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '05 Sep 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '09 Sep 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '12 Sep 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '16 Sep 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '19 Sep 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '23 Sep 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '26 Sep 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '30 Sep 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '03 Oct 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '07 Oct 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '10 Oct 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '14 Oct 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '17 Oct 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '21 Oct 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '24 Oct 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '28 Oct 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '31 Oct 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '04 Nov 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '07 Nov 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '11 Nov 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '14 Nov 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '18 Nov 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '21 Nov 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '25 Nov 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '28 Nov 2022 00:01'	System	20 Nov 2020 10:58:22

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:58:22
Amendment Manager: User entered '02 Dec 2022 23:59'	System	20 Nov 2020 10:58:22

US3552497

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:35:00

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 17:29:33

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:00

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash, LLT: Rash over arms - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 22:19:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 22:19:03
Data point term sent to Coder	System	30 Oct 2020 17:30:30
User entered 'rash to left arm'	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:00

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:00

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:00

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '03 Oct 2020' reason for change: Data Entry Error	Heather Douds (b) (4)	09 Nov 2020 18:32:44
User entered '3 Oct 2020'	Stanley Dublin (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:00

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:00

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:00

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '06 Oct 2020' reason for change: Data Entry Error	Heather Douds (b) (4)	09 Nov 2020 18:32:44
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	30 Oct 2020 17:30:42
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	30 Oct 2020 17:30:42
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	30 Oct 2020 17:30:28
User entered '6 Oct 2020'	Stanley Dublin (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:00

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:00

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:00

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:00

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:00

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:00

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:00

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:00

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:00

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:00

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:00

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:00

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:00

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Per CDM: As this AE was the primary reason for Dosing discontinuation, Please consider to update Action taken with Investigational product as "Investigational product withdrawn". Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 09:54:01
Query 'Per CDM: As this AE was the primary reason for Dosing discontinuation, Please consider to update Action taken with Investigational product as "Investigational product withdrawn". Thank you.' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	19 Nov 2020 15:39:15
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	19 Nov 2020 15:39:06
User opened query 'Per CDM: As this AE was the primary reason for Dosing discontinuation, Please consider to update Action taken with Investigational product as "Investigational product withdrawn". Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 11:10:41
User entered 'None (NONE)'	Stanley Doublin (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:00

[None](#)

Audit	User	Time (GMT)
User entered '1'	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:00

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:00

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:00

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Stanley Dublin (b) (4)	30 Oct 2020 17:30:42
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 17:30:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Oct 2020 17:30:28
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Stanley Dublin (b) (4)	30 Oct 2020 17:30:28
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 17:30:20
User entered empty.	Stanley Dublin (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:00

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:00

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:00

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:00

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Oct 2020 17:30:20

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:35:00

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:17:06

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:35:00

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAUTERINE CONTRACEPTIVES, PRODUCT: LEVONORGESTREL, PRODUCTSYNONYM: LILETTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 17:34:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 17:34:34
Data point term sent to Coder	System	29 Sep 2020 17:34:22
Coding entries removed.	Stanley Doublin (b) (4)	29 Sep 2020 17:33:24
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAUTERINE CONTRACEPTIVES, PRODUCT: LEVONORGESTREL, PRODUCTSYNONYM: LILETTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 11:25:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 11:25:53
Data point term sent to Coder	System	28 Sep 2020 12:24:03
User entered 'LILETTA IUD' reason for change:	Stanley Doublin (b) (4)	28 Sep 2020 12:23:50
Data Entry Error	(b) (4)	
Data point term sent to Coder	System	28 Sep 2020 12:18:52
User entered 'lilletta IUD'	Stanley Doublin (b) (4)	28 Sep 2020 12:18:44
	(b) (4)	

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:35:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:18:44

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:35:00

[Indication](#)

Audit	User	Time (GMT)
User entered 'birth control'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:18:44

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:35:00

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 17:34:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Sep 2020 17:34:09
User entered '52' reason for change: Data Entry Error	Stanley Dublin (b) (4)	29 Sep 2020 17:34:09
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 12:18:44
User entered empty.	Stanley Dublin (b) (4)	28 Sep 2020 12:18:44

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:35:00

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 17:34:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Sep 2020 17:34:09
User entered 'mg (mg)' reason for change: Data Entry Error	Stanley Doublin (b) (4)	29 Sep 2020 17:34:09
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 12:18:44
User entered empty.	Stanley Doublin (b) (4)	28 Sep 2020 12:18:44

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:35:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:18:44

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:35:00

[Frequency](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 17:33:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Sep 2020 17:33:24
User entered 'once (ONCE)' reason for change: Data Entry Error	Stanley Doublin (b) (4)	29 Sep 2020 17:33:24
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 12:18:44
User entered empty.	Stanley Doublin (b) (4)	28 Sep 2020 12:18:44

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:35:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:18:44

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:35:00

[Route of administration](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 17:33:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Sep 2020 17:33:24
User entered 'Vaginal (VAGINAL)' reason for change: Data Entry Error	Stanley Dublin (b) (4)	29 Sep 2020 17:33:24
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 12:18:44
User entered empty.	Stanley Dublin (b) (4)	28 Sep 2020 12:18:44

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:35:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:18:44

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2017'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:18:44

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:35:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:18:44

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:35:00

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:18:44

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:35:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:18:44

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:35:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:18:44

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:35:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 12:18:44

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:35:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 12:18:44

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:35:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 12:18:44

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:35:00

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 12:21:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 12:21:40
Data point term sent to Coder	System	28 Sep 2020 12:21:01
User entered 'levothyroxine'	Stanley Doublin (b) (4)	28 Sep 2020 12:20:21

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:35:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:20:21

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:35:00

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypothyroidism'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:20:21

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:35:00

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '175/150'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:20:21

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:35:00

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:20:21

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:35:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:20:21

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:35:00

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:20:21

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:35:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:20:21

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:35:00

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:20:21

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:35:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:20:21

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2016'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:20:21

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:35:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:20:21

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:35:00

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:20:21

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:35:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:20:21

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:35:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:20:21

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:35:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 12:20:21

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:35:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 12:20:21

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:35:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 12:20:21

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:35:00

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 12:23:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 12:23:36
Data point term sent to Coder	System	28 Sep 2020 12:23:02
User entered 'vitamin d'	Stanley Dublin (b) (4)	28 Sep 2020 12:22:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:35:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR - Requery: Response noted, however, please update the field according the latest guidelines (pg 40 eCRF Guidelines v2.0 23Oct2020). ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 05:55:42
Query 'Per DM CLR - Requery: Response noted, however, please update the field according the latest guidelines (pg 40 eCRF Guidelines v2.0 23Oct2020). ' answered with 'updated to prophylaxis' (Site from DM).	Mikayla Frye (b) (4) (b) (4)	11 Nov 2020 16:11:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Mikayla Frye (b) (4) (b) (4)	11 Nov 2020 16:11:45
User opened query 'Per DM CLR - Requery: Response noted, however, please update the field according the latest guidelines (pg 40 eCRF Guidelines v2.0 23Oct2020). ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 14:49:20
User closed query 'Per DM CLR: Prophylaxis= NO. However, the conmed appears to be a supplement.Please review if this should be more appropriately marked as YES to match the conmed indication. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 14:49:20
Query 'Per DM CLR: Prophylaxis= NO. However, the conmed appears to be a supplement.Please review if this should be more appropriately marked as YES to match the conmed indication. Update as appropriate. ' answered with 'At the time we were advised against entering vitamins and supplements as "prophylaxis". Will keep entered data as is and enter any new data according to new guidelines. Thank you' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	02 Nov 2020 15:39:15
User opened query 'Per DM CLR: Prophylaxis= NO. However, the conmed appears to be a supplement.Please review if this should be more appropriately marked as YES to match the conmed indication. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 05:32:34
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:22:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:35:00

[Indication](#)

Audit	User	Time (GMT)
User entered 'health promotion'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:22:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:35:00

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 07:14:07
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'subject reported data, exact dosage unknown' (Site from DM).	Cassandra Zehenny (b) (4)	02 Nov 2020 15:39:24
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 05:32:37
Data hard unlocked.	(b) (4), (b) (6)	02 Nov 2020 05:32:21
Data hard locked.	(b) (4), (b) (6)	02 Nov 2020 05:32:18
User entered '1'	Stanley Dublin (b) (4)	28 Sep 2020 12:22:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:35:00

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'tablet (TABLET)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:22:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:35:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:22:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:35:00

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:22:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:35:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:22:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:35:00

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:22:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:35:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:22:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:22:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:35:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:22:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:35:00

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:22:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:35:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:22:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:35:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:22:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:35:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 12:22:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:35:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 12:22:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:35:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 12:22:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:35:00

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: BIOTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 12:24:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 12:24:39
Data point term sent to Coder	System	28 Sep 2020 12:24:03
User entered 'biotin'	Stanley Doublin (b) (4)	28 Sep 2020 12:23:16

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:35:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR - Requery: Response noted, however, please update the field according the latest guidelines (pg 40 eCRF Guidelines v2.0 23Oct2020).' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 05:55:47
Query 'Per DM CLR - Requery: Response noted, however, please update the field according the latest guidelines (pg 40 eCRF Guidelines v2.0 23Oct2020).' answered with 'updated to prophylaxis' (Site from DM).	Mikayla Frye (b) (4)	11 Nov 2020 16:11:56
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 16:11:52
User opened query 'Per DM CLR - Requery: Response noted, however, please update the field according the latest guidelines (pg 40 eCRF Guidelines v2.0 23Oct2020).' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 14:49:35
User closed query 'Per DM CLR: Prophylaxis= NO. However, the conmed appears to be a supplement.Please review if this should be more appropriately marked as YES to match the conmed indication. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 14:49:35
Query 'Per DM CLR: Prophylaxis= NO. However, the conmed appears to be a supplement.Please review if this should be more appropriately marked as YES to match the conmed indication. Update as appropriate. ' answered with 'At the time we were advised against entering vitamins and supplements as "prophylaxis". Will keep entered data as is and enter any new data according to new guidelines. Thank you' (Site from DM).	Cassandra Zehenny (b) (4)	02 Nov 2020 15:39:28
User opened query 'Per DM CLR: Prophylaxis= NO. However, the conmed appears to be a supplement.Please review if this should be more appropriately marked as YES to match the conmed indication. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 05:33:33
User entered 'No (N)'	Stanley Dublin (b) (4)	28 Sep 2020 12:23:16

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:35:00

[Indication](#)

Audit	User	Time (GMT)
User entered 'health promotion'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:23:16

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:35:00

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Prophylaxis= NO. However, the conmed appears to be a supplement.Please review if this should be more appropriately marked as YES to match the conmed indication. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 07:36:41
Query 'Per DM CLR: Prophylaxis= NO. However, the conmed appears to be a supplement.Please review if this should be more appropriately marked as YES to match the conmed indication. Update as appropriate. ' answered with 'subject reported data, exact dosage unknown' (Site from DM).	Cassandra Zehenny (b) (4)	02 Nov 2020 15:39:39
User opened query 'Per DM CLR: Prophylaxis= NO. However, the conmed appears to be a supplement.Please review if this should be more appropriately marked as YES to match the conmed indication. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 05:33:46
User entered '1'	Stanley Dublin (b) (4)	28 Sep 2020 12:23:16

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:35:00

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'tablet (TABLET)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:23:16

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:35:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:23:16

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:35:00

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:23:16

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:35:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:23:16

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:35:00

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:23:16

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:35:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:23:16

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered 'un May 2020'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:23:16

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:35:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:23:16

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:35:00

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:23:16

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:35:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:23:16

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:35:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:23:16

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:35:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 12:23:16

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:35:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 12:23:16

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:35:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 12:23:16

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:35:00

[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)	20 Nov 2020 16:41:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 16:41:05
Data point term sent to Coder	System	20 Nov 2020 16:09:08
Coding entries removed.	Stanley Doublin (b) (4) (b) (4)	20 Nov 2020 16:08:14
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 Oct 2020 17:26:21
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 Oct 2020 17:26:21
Data point term sent to Coder	System	19 Oct 2020 17:25:11
User entered 'influenza vaccine'	Joan Siegner (b) (4) (b) (4) (b) (4)	19 Oct 2020 17:24:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:35:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joan Siegner (b) (4)	19 Oct 2020 17:24:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:35:00

[Indication](#)

Audit	User	Time (GMT)
User entered 'INFLUENZA PROPHYLAXIS'	Stanley Dublin (b) (4)	20 Nov 2020 16:08:14
reason for change: Data Entry Error	(b) (4)	
User entered 'prophylaxis'	Joan Siegner (b) (4)	19 Oct 2020 17:24:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:35:00

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Joan Siegner (b) (4)	19 Oct 2020 17:24:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:35:00

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Joan Siegner (b) (4)	19 Oct 2020 17:24:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:35:00

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered 'cc'	Joan Siegner (b) (4)	19 Oct 2020 17:24:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:35:00

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Joan Siegner (b) (4)	19 Oct 2020 17:24:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:35:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Joan Siegner (b) (4)	19 Oct 2020 17:24:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:35:00

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	Joan Siegner (b) (4)	19 Oct 2020 17:24:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:35:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Joan Siegner (b) (4)	19 Oct 2020 17:24:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:35:00

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

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Joan Siegner (b) (4)	19 Oct 2020 17:24:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:35:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joan Siegner (b) (4)	19 Oct 2020 17:24:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:35:00

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joan Siegner (b) (4)	19 Oct 2020 17:24:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:35:00

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Joan Siegner (b) (4)	19 Oct 2020 17:24:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:35:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joan Siegner (b) (4)	19 Oct 2020 17:24:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:35:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 17:24:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:35:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 17:24:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:35:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 17:24:47

US3552497

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:35:00

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '29 Oct 2020'	Heather Douds (b) (4) (b) (4)	10 Nov 2020 17:00:47

US3552497

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:35:00

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User entered 'AE (specify) (ADVERSE EVENT)'	Heather Douds (b) (4) (b) (4)	10 Nov 2020 17:00:47

US3552497

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:35:00

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User closed query 'Please specify AE - RASH TO LEFT ARM' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 02:06:54
Query 'Please specify AE - RASH TO LEFT ARM' answered with 'I received a query this morning asking me to reference the AE # instead of AE event. Please advise which is correct. ' (Site from CRA).	Cassandra Zehenny (b) (4)	18 Nov 2020 22:26:18
User opened query 'Please specify AE - RASH TO LEFT ARM' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 17:12:49
User closed query 'Please update entry to specify AE - RASH TO LEFT ARM' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 17:12:18
Query 'Please update entry to specify AE - RASH TO LEFT ARM' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4)	18 Nov 2020 16:20:04
User entered 'AE #1' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	18 Nov 2020 16:20:01
User opened query 'Please update entry to specify AE - RASH TO LEFT ARM' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 02:40:07
User entered 'Physician decision, see AE#1'	Heather Douds (b) (4)	10 Nov 2020 17:00:47