

US3552497 (Prod: Saint Louis University)

Generated By: KC Joubran

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US3552497

Form: Participant Creation

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

[Participant ID](#)

US3552497

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

US3552497

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 19:36:13

Generated On: 11 Aug 2021 22:55:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

Date of Birth (MMM yyyy)	(b) (6) 1998
Age	22
Age Units	YEARS
Age (Derived)	22
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 21 Feb 2021 19:36:12

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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 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 21 Feb 2021 19:36:12

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 21 Feb 2021 19:36:13

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Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 21 Feb 2021 19:36:13

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Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN AUG 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 21 Feb 2021 19:36:13

Generated On: 11 Aug 2021 22:55:30

Condition	HYPOTHYROIDISM HASHIMOTO DX
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN 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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 21 Feb 2021 19:36:13

Generated On: 11 Aug 2021 22:55:30

Condition	THYROIDECTOMY
Start date (dd MMM yyyy)	UN MAR 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN 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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 21 Feb 2021 19:36:13

Generated On: 11 Aug 2021 22:55:30

Condition	ALLERGY TO THIAMAZOLE
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 21 Feb 2021 19:36:13

Generated On: 11 Aug 2021 22:55:30

Condition	CHILDHOOD ASTHMA
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 21 Feb 2021 19:36:13

Generated On: 11 Aug 2021 22:55:30

Condition	KELOID LESIONS ON CHEST
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 19:36:13

Generated On: 11 Aug 2021 22:55:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
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
Height (xxx.x)	65 in
Weight (xxx.x)	195 lb
BMI (xxx.x)	32.51755 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 19:36:13

Generated On: 11 Aug 2021 22:55:30

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.

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 21 Feb 2021 19:36:12

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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

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 21 Feb 2021 19:36:13

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 21 Feb 2021 19:36:13

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify

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

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

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EAB) (1725)

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 21 Feb 2021 19:36:13

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 19:36:34

Generated On: 11 Aug 2021 22:55:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 21 Feb 2021 19:36:34

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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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 21 Feb 2021 19:36:34

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 19:36:34

Generated On: 11 Aug 2021 22:55:30

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	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 <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 19:36:34

Generated On: 11 Aug 2021 22:55:30

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	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 <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
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

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 19:36:34

Generated On: 11 Aug 2021 22:55:30

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 21 Feb 2021 19:36:34

Generated On: 11 Aug 2021 22:55:30

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) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 19:36:13

Generated On: 11 Aug 2021 22:55:30

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 19:36:34

Generated On: 11 Aug 2021 22:55:30

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 SEP 2020
Collection time (00:00-23:59)	13:45 (24 HR)
Collection date and time (derived)	26 SEP 2020 13:45

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Feb 2021 19:36:13

Generated On: 11 Aug 2021 22:55:30

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

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:36:13

Generated On: 11 Aug 2021 22:55:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:30

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:30

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:30

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

50 of 1622

EAB) (1725)

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:30

Yes <input type="checkbox"/>	
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: 11 Aug 2021 22:55:30

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

52 of 1622

EAB) (1725)

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:30

		Yes <input type="checkbox"/>
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: 11 Aug 2021 22:55:30

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

54 of 1622

EAB) (1725)

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:30

Yes <input type="checkbox"/>	
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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

		Yes <input type="checkbox"/>
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: 11 Aug 2021 22:55:30

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

58 of 1622

EAB) (1725)

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:30

Yes <input type="checkbox"/>	
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: 11 Aug 2021 22:55:30

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

60 of 1622

EAB) (1725)

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:30

Yes <input type="checkbox"/>	
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

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

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

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552497

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

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

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552497

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

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

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552497

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 19:36:35

Generated On: 11 Aug 2021 22:55:30

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

Visit date (dd MMM yyyy)	29 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 19:36:35

Generated On: 11 Aug 2021 22:55:30

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 OCT 2020
Time of assessment (00:00-23:59)	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 <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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)

Data signed: (b) (4) 21 Feb 2021 19:36:35

Generated On: 11 Aug 2021 22:55:30

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
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 <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
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

Data signed: (b) (4) 21 Feb 2021 19:36:35

Generated On: 11 Aug 2021 22:55:30

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

Data signed: (b) (4) 21 Feb 2021 19:36:35

Generated On: 11 Aug 2021 22:55:30

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

US3552497

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 19:36:35

Generated On: 11 Aug 2021 22:55:30

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

Data signed: (b) (4) 21 Feb 2021 19:36:35

Generated On: 11 Aug 2021 22:55:30

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 OCT 2020
Collection time (00:00-23:59)	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

Data signed: (b) (4) 21 Feb 2021 19:36:35

Generated On: 11 Aug 2021 22:55:30

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

Data signed: (b) (4) 21 Feb 2021 19:36:35

Generated On: 11 Aug 2021 22:55:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552497

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

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

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552497

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

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

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552497

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

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

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552497

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 19:36:35

Generated On: 11 Aug 2021 22:55:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3552497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 19:36:35

Generated On: 11 Aug 2021 22:55:30

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3552497

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 19:36:35

Generated On: 11 Aug 2021 22:55:30

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

Data signed: (b) (4) 21 Feb 2021 19:36:35

Generated On: 11 Aug 2021 22:55:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

20 NOV 2020

Collection time (00:00-23:59)

08:42 (24 HR)

Collection date and time (derived)

20 NOV 2020 08:42

US3552497

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:36:35

Generated On: 11 Aug 2021 22:55:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

Date and time of submission

26 NOV 2020 00:31:19

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: 11 Aug 2021 22:55:30

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 NOV 2020 06:50:38
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: 11 Aug 2021 22:55:30

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 DEC 2020 12:00:14
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: 11 Aug 2021 22:55:30

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 DEC 2020 00:01:15
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: 11 Aug 2021 22:55:30

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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: 11 Aug 2021 22:55:30

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 DEC 2020 00:01:15
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: 11 Aug 2021 22:55:30

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 JAN 2021 12:57:47

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: 11 Aug 2021 22:55:30

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 JAN 2021 23:50:53
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: 11 Aug 2021 22:55:30

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 JAN 2021 09:49:08
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: 11 Aug 2021 22:55:30

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 JAN 2021 00:11:46
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: 11 Aug 2021 22:55:30

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 FEB 2021 00:02:06
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: 11 Aug 2021 22:55:30

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 FEB 2021 14:49:18
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: 11 Aug 2021 22:55:30

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 FEB 2021 00:01:35
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: 11 Aug 2021 22:55:30

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 FEB 2021 22:38:41

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: 11 Aug 2021 22:55:30

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 MAR 2021 17:57:42
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: 11 Aug 2021 22:55:30

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 MAR 2021 11:22:02

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: 11 Aug 2021 22:55:30

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 MAR 2021 15:11:30

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: 11 Aug 2021 22:55:30

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 MAR 2021 00:19:06
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: 11 Aug 2021 22:55:30

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 MAR 2021 01:38:04
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: 11 Aug 2021 22:55:30

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 APR 2021 12:39:37
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: 11 Aug 2021 22:55:30

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 18:13:06

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: 11 Aug 2021 22:55:30

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 APR 2021 00:03:54

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: 11 Aug 2021 22:55:30

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

[Patient Cloud Open Date & Time](#)

03 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

[Patient Cloud Open Date & Time](#)

10 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

[Patient Cloud Open Date & Time](#)

31 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

[Patient Cloud Open Date & Time](#)

16 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

[Patient Cloud Open Date & Time](#)

30 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

[Patient Cloud Open Date & Time](#)

06 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: 11 Aug 2021 22:55:30

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

[Patient Cloud Open Date & Time](#)

20 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: 11 Aug 2021 22:55:30

TIMEPOINT	DAY 369
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

[Patient Cloud Open Date & Time](#)

04 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

[Patient Cloud Open Date & Time](#)

11 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

[Patient Cloud Open Date & Time](#)

18 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

[Patient Cloud Open Date & Time](#)

13 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

[Patient Cloud Open Date & Time](#)

20 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

[Patient Cloud Open Date & Time](#)

27 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

[Patient Cloud Open Date & Time](#)

03 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

[Patient Cloud Open Date & Time](#)

07 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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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

[Patient Cloud Open Date & Time](#)

14 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

[Patient Cloud Open Date & Time](#)

21 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: 11 Aug 2021 22:55:30

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°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: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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

[Patient Cloud Open Date & Time](#)

18 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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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

[Patient Cloud Open Date & Time](#)

09 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

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06 JUN 2022 00:01

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10 JUN 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

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13 JUN 2022 00:01

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17 JUN 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

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20 JUN 2022 00:01

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24 JUN 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

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01 JUL 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

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04 JUL 2022 00:01

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08 JUL 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

[Patient Cloud Open Date & Time](#)

11 JUL 2022 00:01

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15 JUL 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

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22 JUL 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

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29 JUL 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

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05 AUG 2022 23:59

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

[Patient Cloud Open Date & Time](#)

22 AUG 2022 00:01

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26 AUG 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

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29 AUG 2022 00:01

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02 SEP 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

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05 SEP 2022 00:01

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09 SEP 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

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16 SEP 2022 23:59

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

[Patient Cloud Open Date & Time](#)

03 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

[Patient Cloud Open Date & Time](#)

10 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

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

US3552497

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Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

[Patient Cloud Open Date & Time](#)

24 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: 11 Aug 2021 22:55:30

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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

[Patient Cloud Open Date & Time](#)

14 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: 11 Aug 2021 22:55:30

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

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

[Patient Cloud Open Date & Time](#)

21 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: 11 Aug 2021 22:55:30

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:55:30

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		03 MAR 2021 17:57:36

US3552497

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 DEC 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 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552497

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

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 119 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552497

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 03:32:34

Generated On: 11 Aug 2021 22:55:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552497

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:32:34

Generated On: 11 Aug 2021 22:55:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552497

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Mar 2021 15:44:41

Generated On: 11 Aug 2021 22:55:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 MAR 2021

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 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 18:04:58

Generated On: 11 Aug 2021 22:55:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552497

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 18:05:01

Generated On: 11 Aug 2021 22:55:30

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

Visit date (dd MMM yyyy)	13 APR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3552497

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 18:05:01

Generated On: 11 Aug 2021 22:55:30

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3552497

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 18:04:58

Generated On: 11 Aug 2021 22:55:30

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 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 18:04:58

Generated On: 11 Aug 2021 22:55:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 APR 2021

Collection time (00:00-23:59)

12:38 (24 HR)

Collection date and time (derived)

13 APR 2021 12:38

US3552497

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 18:04:58

Generated On: 11 Aug 2021 22:55:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552497

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552497

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:30

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3552497

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:55:30

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

US3552497

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:55:30

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3552497

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

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

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

Visit date (dd MMM yyyy)	20 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3552497

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

Form: Unblinding

Data signed: (b) (4) 23 Mar 2021 15:44:41

Generated On: 11 Aug 2021 22:55:30

Date of updated informed consent (<i>dd MMM yyyy</i>)	20 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	20 JAN 2021
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	1

US3552497

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

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

US3552497

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 JAN 2021
Time of assessment (00:00-23:59)	13:10 (24 HR)
Vital Signs Date and Time (derived)	20 JAN 2021 13:10
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3552497

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 JAN 2021
Time of assessment (00:00-23:59)	14:06 (24 HR)
Vital Signs Date and Time (derived)	20 JAN 2021 14:06
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3552497

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

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 JAN 2021

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

US3552497

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

Form: Pregnancy Test

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	20 JAN 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	20 JAN 2021
Collection time	13:25
Collection date and time (derived)	20 JAN 2021 13:25

US3552497

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

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 20 JAN 2021

What was the treatment time? (00:00-23:59) 13:36 (24 HR)

Treatment Date and Time (derived) 20 JAN 2021 13:36

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: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

20 JAN 2021

Collection time (00:00-23:59)

12:57 (24 HR)

Collection date and time (derived)

20 JAN 2021 12:57

US3552497

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	20 JAN 2021
Collection time (00:00 - 23:59)	13:00
Collection Date and Time (derived)	20 JAN 2021 13:00

US3552497

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

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552497

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 JAN 2021

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 OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

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

US3552497

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 03:32:34

Generated On: 11 Aug 2021 22:55:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3552497

Folder: OL-D29 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Feb 2021 03:32:34

Generated On: 11 Aug 2021 22:55:30

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3552497

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 03:32:34

Generated On: 11 Aug 2021 22:55:30

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Feb 2021 03:32:34

Generated On: 11 Aug 2021 22:55:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 FEB 2021

Collection time (00:00-23:59)

10:46 (24 HR)

Collection date and time (derived)

24 FEB 2021 10:46

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Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

AEID	
Adverse event	URTICARIAL INJECTION SITE RASH TO LEFT ARM
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	03 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	06 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

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

CONTINUOUS

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	INTRAUTERINE	
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN MAY 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	13 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication PAIN AT INJECTION SITE,
FEVER, CHILLS, BODY ACHES

Dose per administration 600

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3552497

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Feb 2021 03:32:34

Generated On: 11 Aug 2021 22:55:30

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

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Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 21 Feb 2021 19:36:12

Generated On: 11 Aug 2021 22:55:30

Date of dosing discontinuation (dd MMM yyyy)	29 OCT 2020
----------------------------------------------	-------------

Primary reason for dosing discontinuation	AE (specify) <input checked="" type="radio"/>
	SAE (specify) <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-up <input type="radio"/>
	Physician decision (specify) <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol deviation (specify) <input type="radio"/>
	Study Terminated By Sponsor <input type="radio"/>
	Withdrawal of consent by participant (specify) <input type="radio"/>
	Due to SARS-COV-2 <input type="radio"/>
	Other <input type="radio"/>

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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'US3552497'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Sep 2020 18:17:34

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Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:55:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:04:41

US3552497

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:55:30

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '26 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Sep 2020 18:17:35

US3552497

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:04:41

US3552497

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:55:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered 'SCRN'	System	28 Sep 2020 12:04:41

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Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:30

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered (b) (6) 1998'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Sep 2020 18:17:36

US3552497

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:30

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '22'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:05:17

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Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:30

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered 'YEARS'	System	28 Sep 2020 12:05:17

US3552497

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:30

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered '22'	System	26 Sep 2020 19:13:17

US3552497

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:30

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Female (F)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:05:17

US3552497

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:30

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:05:17

US3552497

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:30

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:05:17

US3552497

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:30

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:05:17

US3552497

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:30

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'l'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:05:17

US3552497

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:30

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:05:17

US3552497

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:30

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:05:17

US3552497

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:30

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:05:17

US3552497

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:30

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:05:17

US3552497

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:30

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:05:17

US3552497

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:30

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:05:17

US3552497

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:30

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '26 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 19:13:17

US3552497

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered 'Sep 2020'	System	26 Sep 2020 19:13:17

US3552497

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered '2020'	System	26 Sep 2020 19:13:17

US3552497

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:30

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	26 Sep 2020 19:13:17

US3552497

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 19:13:17

US3552497

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:30

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 19:13:17

US3552497

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:30

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 19:13:17

US3552497

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:30

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:36:14
User entered 'No (N)'	(b) (4), (b) (6)	26 Sep 2020 19:13:17

US3552497

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:30

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Sep 2020 18:17:35

US3552497

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:30

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered 'l'	System	26 Sep 2020 19:13:22

US3552497

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 19:13:22

US3552497

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:55:30

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:07:01

US3552497

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:55:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User coded data point as SOC: Endocrine disorders, HLT: 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 Dublin (b) (4)	28 Sep 2020 12:07:43

US3552497

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'un Aug 2015'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:07:43

US3552497

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:55:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:07:43

US3552497

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:55:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:07:43

US3552497

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:07:43

US3552497

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:55:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:07:43

US3552497

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:55:30

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered 'Aug 2015'	System	28 Sep 2020 12:07:43

US3552497

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:55:30

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered '2015'	System	28 Sep 2020 12:07:43

US3552497

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered empty.	System	28 Sep 2020 12:07:43

US3552497

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered empty.	System	28 Sep 2020 12:07:43

US3552497

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:55:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:36:14
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 Doublin (b) (4) (b) (4)	28 Sep 2020 12:08:41

US3552497

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'un UNK 2014'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:08:41

US3552497

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:55:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:08:41

US3552497

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:55:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:08:41

US3552497

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'un Mar 2015'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:08:41

US3552497

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:55:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:08:41

US3552497

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered 'Jan 2014'	System	28 Sep 2020 12:08:41

US3552497

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:55:30

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered '2014'	System	28 Sep 2020 12:08:41

US3552497

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered 'Mar 2015'	System	28 Sep 2020 12:08:41

US3552497

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered '2015'	System	28 Sep 2020 12:08:41

US3552497

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:55:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:36:14
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 Doublin (b) (4) (b) (4)	28 Sep 2020 12:09:12

US3552497

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'un Mar 2015'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:09:12

US3552497

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:55:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:09:12

US3552497

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:55:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:09:12

US3552497

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'un Mar 2015'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:09:12

US3552497

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:55:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:09:12

US3552497

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered 'Mar 2015'	System	28 Sep 2020 12:09:12

US3552497

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:55:30

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered '2015'	System	28 Sep 2020 12:09:12

US3552497

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered 'Mar 2015'	System	28 Sep 2020 12:09:12

US3552497

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered '2015'	System	28 Sep 2020 12:09:12

US3552497

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:55:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:36:14
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 Doublin (b) (4) (b) (4)	28 Sep 2020 12:10:12

US3552497

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'un UNK 2015'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:10:12

US3552497

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:55:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:10:12

US3552497

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:55:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:10:12

US3552497

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:10:12

US3552497

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:55:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:10:12

US3552497

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered 'Jan 2015'	System	28 Sep 2020 12:10:12

US3552497

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:55:30

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered '2015'	System	28 Sep 2020 12:10:12

US3552497

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered empty.	System	28 Sep 2020 12:10:12

US3552497

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered empty.	System	28 Sep 2020 12:10:12

US3552497

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:55:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
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)	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)	28 Sep 2020 12:12:47
Data point term sent to Coder	System	28 Sep 2020 12:11:46
User entered 'childhood asthma'	Stanley Doublin (b) (4)	28 Sep 2020 12:10:48

US3552497

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'un UNK 2002'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:10:48

US3552497

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:55:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:10:48

US3552497

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:55:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:10:48

US3552497

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'un UNK 2006'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:10:48

US3552497

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:55:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:10:48

US3552497

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered 'Jan 2002'	System	28 Sep 2020 12:10:48

US3552497

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:55:30

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered '2002'	System	28 Sep 2020 12:10:48

US3552497

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered 'Jan 2006'	System	28 Sep 2020 12:10:48

US3552497

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered '2006'	System	28 Sep 2020 12:10:48

US3552497

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:55:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:36:14
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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'un UNK 2016'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:11:29

US3552497

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:55:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:11:29

US3552497

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:55:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:11:29

US3552497

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:11:29

US3552497

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:55:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:11:29

US3552497

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:55:30

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered 'Jan 2016'	System	28 Sep 2020 12:11:29

US3552497

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:55:30

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered '2016'	System	28 Sep 2020 12:11:29

US3552497

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered empty.	System	28 Sep 2020 12:11:29

US3552497

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered empty.	System	28 Sep 2020 12:11:29

US3552497

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:12:02

US3552497

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '26 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:12:02

US3552497

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '13:09'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:12:02

US3552497

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered '26 Sep 2020 13:09'	System	28 Sep 2020 12:12:02

US3552497

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '65' in	(b) (4)	
	Stanley Dublin (b) (4)	28 Sep 2020 12:12:02
	(b) (4)	
DataPoint set to visible.	System	26 Sep 2020 19:13:22

US3552497

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '195' lb	(b) (4) 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: 11 Aug 2021 22:55:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
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: 11 Aug 2021 22:55:30

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
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: 11 Aug 2021 22:55:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:12:02

US3552497

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:12:02

US3552497

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:12:02

US3552497

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:12:02

US3552497

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered 'bpm'	System	28 Sep 2020 12:12:02

US3552497

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered missing code ND - Not Done.	(b) (4) Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:12:02

US3552497

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered 'breaths/min'	System	28 Sep 2020 12:12:02

US3552497

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:12:02

US3552497

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered 'mmHg'	System	28 Sep 2020 12:12:02

US3552497

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:12:02

US3552497

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered 'mmHg'	System	28 Sep 2020 12:12:02

US3552497

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49

US3552497

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49

US3552497

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:12:10

US3552497

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:30

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '26 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:12:10

US3552497

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:55:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '26 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:12:33

US3552497

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:12:33

US3552497

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:12:33

US3552497

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:55:30

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:12:33

US3552497

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:12:33

US3552497

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:55:30

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:12:33

US3552497

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:12:33

US3552497

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:55:30

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:12:33

US3552497

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:30

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:13:13

US3552497

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:30

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '26 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:13:13

US3552497

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:30

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Urine (URINE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:13:13

US3552497

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:30

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Negative (NEGATIVE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:13:13

US3552497

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:30

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:13:13

US3552497

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:30

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:13:13

US3552497

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:30

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:13:13

US3552497

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered empty.	System	28 Sep 2020 12:13:13

US3552497

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:15

US3552497

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:15

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:36:14
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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:36:14
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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:15

US3552497

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:36:14
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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:15

US3552497

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:36:14
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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:15

US3552497

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:15

US3552497

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:36:14
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: 11 Aug 2021 22:55:30

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:15

US3552497

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:30

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:36:14
User entered 'occupational therapy student, grocery shopping, nail salon, dine (outdoors)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:15

US3552497

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:30

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:15

US3552497

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:15

US3552497

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:36:14
User entered '0'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:14:15

US3552497

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'l'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:15

US3552497

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:15

US3552497

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:15

US3552497

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:30

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:15

US3552497

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:30

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:15

US3552497

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:55:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:29

US3552497

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered '26 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:29

US3552497

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:29

US3552497

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:55:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User entered 'VISIT1'	System	28 Sep 2020 12:14:29

US3552497

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered '26 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Sep 2020 19:02:34

US3552497

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered '115802'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Sep 2020 19:02:34

US3552497

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Sep 2020 19:02:34

US3552497

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:14:43

US3552497

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:14:43

US3552497

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:43

US3552497

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:55:30

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:43

US3552497

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:55:30

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:14:43

US3552497

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 22:55:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:15:22

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:15:22

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:15:22

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered missing code ND - Not Done.	(b) (4) 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: 11 Aug 2021 22:55:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
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: 11 Aug 2021 22:55:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered 'Yes (Y)'	(b) (4) 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: 11 Aug 2021 22:55:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered '26 Sep 2020'	(b) (4) 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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered '13:09'	(b) (4) 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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
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: 11 Aug 2021 22:55:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered '98.8' F	(b) (4) 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: 11 Aug 2021 22:55:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered 'Oral (Oral)'	(b) (4) 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: 11 Aug 2021 22:55:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered empty.	(b) (4) 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: 11 Aug 2021 22:55:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered '68'	(b) (4) 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: 11 Aug 2021 22:55:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User entered 'bpm'	System	28 Sep 2020 12:15:22

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered '16'	(b) (4) 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: 11 Aug 2021 22:55:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User entered 'breaths/min'	System	28 Sep 2020 12:15:22

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered '109'	(b) (4) 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: 11 Aug 2021 22:55:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User entered 'mmHg'	System	28 Sep 2020 12:15:22

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered '77'	(b) (4) 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: 11 Aug 2021 22:55:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User entered 'mmHg'	System	28 Sep 2020 12:15:22

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:15:22

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered missing code ND - Not Done.	(b) (4) 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: 11 Aug 2021 22:55:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:15:59

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered 'Yes (Y)'	(b) (4) 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: 11 Aug 2021 22:55:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered '26 Sep 2020'	(b) (4) 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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered '14:55'	(b) (4) 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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
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: 11 Aug 2021 22:55:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:36:35
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: 11 Aug 2021 22:55:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered 'Oral (Oral)'	(b) (4) 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: 11 Aug 2021 22:55:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered empty.	(b) (4) 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: 11 Aug 2021 22:55:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered '60'	(b) (4) 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: 11 Aug 2021 22:55:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User entered 'bpm'	System	28 Sep 2020 12:15:59

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered '16'	(b) (4) 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: 11 Aug 2021 22:55:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User entered 'breaths/min'	System	28 Sep 2020 12:15:59

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered '118'	(b) (4) 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: 11 Aug 2021 22:55:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User entered 'mmHg'	System	28 Sep 2020 12:15:59

US3552497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered '78'	(b) (4) 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: 11 Aug 2021 22:55:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User entered 'mmHg'	System	28 Sep 2020 12:15:59

US3552497

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Stanley Dublin (b) (4)	28 Sep 2020 12:16:27
User entered 'Yes (Y)'	(b) (4)	
	Stanley Dublin (b) (4)	28 Sep 2020 12:16:08
	(b) (4)	

US3552497

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered empty; reason for change Data Entry Error	(b) (4)	
	Stanley Dublin (b) (4)	28 Sep 2020 12:16:27
User entered '26 Sep 2020'	(b) (4)	
	Stanley Dublin (b) (4)	28 Sep 2020 12:16:08
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:30

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:16:16

US3552497

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:30

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:16:16

US3552497

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:30

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:16:16

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:30

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:16:16

US3552497

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:30

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:16:16

US3552497

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:30

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:16:16

US3552497

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:30

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:16:16

US3552497

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:30

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User entered empty.	System	28 Sep 2020 12:16:16

US3552497

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:55:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 19:32:56

US3552497

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:55:30

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 19:32:56

US3552497

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 19:32:56

US3552497

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:55:30

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User entered 'MRNA-1273 OR PLACEBO'	System	26 Sep 2020 19:32:56

US3552497

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:55:30

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '14:25'	(b) (4), (b) (6)	26 Sep 2020 19:32:56

US3552497

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User entered '26 Sep 2020 14:25'	System	26 Sep 2020 19:32:56

US3552497

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 19:32:56

US3552497

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User entered 'ONCE'	System	26 Sep 2020 19:32:56

US3552497

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:55:30

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User entered 'INTRAMUSCULAR'	System	26 Sep 2020 19:32:56

US3552497

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:16:46

US3552497

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered '26 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:16:46

US3552497

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered '13:45'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:16:46

US3552497

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
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: 11 Aug 2021 22:55:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '26 Sep 2020'	(b) (4) 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: 11 Aug 2021 22:55:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:16:58

US3552497

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:55:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) 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: 11 Aug 2021 22:55:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '13:50'	(b) (4) 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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
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: 11 Aug 2021 22:55:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:16:58

US3552497

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:55:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 22:55:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) 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: 11 Aug 2021 22:55:30

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User entered empty.	System	28 Sep 2020 12:16:58

US3552497

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Oct 2020 14:01:25

US3552497

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:55:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User entered 'I'	System	05 Oct 2020 14:01:25

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'Yes (Y)'	System	26 Sep 2020 19:54:07
	System	26 Sep 2020 19:54:07

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered '98.4'	System	26 Sep 2020 19:54:07
	System	26 Sep 2020 19:54:07

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'No (N)'	System	26 Sep 2020 19:54:07
	System	26 Sep 2020 19:54:07

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered '26 Sep 2020 14:54'	System	26 Sep 2020 19:54:07
	System	26 Sep 2020 19:54:07

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered '97.9'	System	27 Sep 2020 00:31:33
	System	27 Sep 2020 00:31:33

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered '97.9'	System	27 Sep 2020 18:09:51
	System	27 Sep 2020 18:09:51

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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
	System	28 Sep 2020 22:57:59

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'No (N)'	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: 11 Aug 2021 22:55:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'Yes (Y)'	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: 11 Aug 2021 22:55:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'Yes (Y)'	System	01 Oct 2020 03:43:42
	System	01 Oct 2020 03:43:42

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered '98.1'	System	01 Oct 2020 03:43:42
	System	01 Oct 2020 03:43:42

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'No (N)'	System	01 Oct 2020 03:43:42
	System	01 Oct 2020 03:43:42

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered '30 Sep 2020 22:43'	System	01 Oct 2020 03:43:42
	System	01 Oct 2020 03:43:42

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'Yes (Y)'	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: 11 Aug 2021 22:55:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered '98.1'	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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'No (N)'	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: 11 Aug 2021 22:55:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'Yes (Y)'	System	03 Oct 2020 02:57:33
	System	03 Oct 2020 02:57:33

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered '98.3'	System	03 Oct 2020 02:57:33
	System	03 Oct 2020 02:57:33

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered '02 Oct 2020 21:57'	System	03 Oct 2020 02:57:33
	System	03 Oct 2020 02:57:33

US3552497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered '26 Sep 2020 14:54'	System	26 Sep 2020 19:55:03
	System	26 Sep 2020 19:55:03

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'No (N)'	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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'Yes (Y)'	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: 11 Aug 2021 22:55:30

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered '26 Sep 2020 19:31'	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: 11 Aug 2021 22:55:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'No (N)'	System	27 Sep 2020 18:10:54
	System	27 Sep 2020 18:10:54

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'No (N)'	System	27 Sep 2020 18:10:54
	System	27 Sep 2020 18:10:54

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'None (1)'	System	27 Sep 2020 18:10:54
	System	27 Sep 2020 18:10:54

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered '27 Sep 2020 13:10'	System	27 Sep 2020 18:10:54
	System	27 Sep 2020 18:10:54

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'No (N)'	System	28 Sep 2020 22:58:13
	System	28 Sep 2020 22:58:13

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'No (N)'	System	28 Sep 2020 22:58:13
	System	28 Sep 2020 22:58:13

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'None (1)'	System	28 Sep 2020 22:58:13
	System	28 Sep 2020 22:58:13

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered '28 Sep 2020 17:58'	System	28 Sep 2020 22:58:13
	System	28 Sep 2020 22:58:13

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'No (N)'	System	29 Sep 2020 18:56:36
	System	29 Sep 2020 18:56:36

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'No (N)'	System	29 Sep 2020 18:56:36
	System	29 Sep 2020 18:56:36

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered '29 Sep 2020 13:56'	System	29 Sep 2020 18:56:36
	System	29 Sep 2020 18:56:36

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' 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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'None (1)'	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: 11 Aug 2021 22:55:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered '02 Oct 2020 00:04'	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: 11 Aug 2021 22:55:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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-c8fac82a14d8'	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: 11 Aug 2021 22:55:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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-c8fac82a14d8' User entered 'No (N)'	System	03 Oct 2020 02:57:43
	System	03 Oct 2020 02:57:43

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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-c8fac82a14d8' User entered 'No (N)'	System	03 Oct 2020 02:57:43
	System	03 Oct 2020 02:57:43

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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-c8fac82a14d8'	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: 11 Aug 2021 22:55:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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-c8fac82a14d8' User entered '02 Oct 2020 21:57'	System	03 Oct 2020 02:57:43
	System	03 Oct 2020 02:57:43

US3552497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' 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: 11 Aug 2021 22:55:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'No (N)'	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: 11 Aug 2021 22:55:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'None (0)'	System	27 Sep 2020 00:31:59
	System	27 Sep 2020 00:31:59

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'None (0)'	System	27 Sep 2020 00:31:59
	System	27 Sep 2020 00:31:59

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'None (0)'	System	27 Sep 2020 00:31:59
	System	27 Sep 2020 00:31:59

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'None (0)'	System	27 Sep 2020 00:31:59
	System	27 Sep 2020 00:31:59

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'None (0)'	System	27 Sep 2020 00:31:59
	System	27 Sep 2020 00:31:59

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'None (0)'	System	27 Sep 2020 00:31:59
	System	27 Sep 2020 00:31:59

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'No (N)'	System	27 Sep 2020 00:31:59
	System	27 Sep 2020 00:31:59

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered '26 Sep 2020 19:31'	System	27 Sep 2020 00:31:59
	System	27 Sep 2020 00:31:59

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'None (0)'	System	27 Sep 2020 18:11:10
	System	27 Sep 2020 18:11:10

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'None (0)'	System	27 Sep 2020 18:11:10
	System	27 Sep 2020 18:11:10

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'None (0)'	System	27 Sep 2020 18:11:10
	System	27 Sep 2020 18:11:10

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'None (0)'	System	27 Sep 2020 18:11:10
	System	27 Sep 2020 18:11:10

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'None (0)'	System	27 Sep 2020 18:11:10
	System	27 Sep 2020 18:11:10

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'None (0)'	System	27 Sep 2020 18:11:10
	System	27 Sep 2020 18:11:10

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'No (N)'	System	27 Sep 2020 18:11:10
	System	27 Sep 2020 18:11:10

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered '27 Sep 2020 13:11'	System	27 Sep 2020 18:11:10
	System	27 Sep 2020 18:11:10

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'None (0)'	System	28 Sep 2020 22:58:32
	System	28 Sep 2020 22:58:32

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'None (0)'	System	28 Sep 2020 22:58:32
	System	28 Sep 2020 22:58:32

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'None (0)'	System	28 Sep 2020 22:58:32
	System	28 Sep 2020 22:58:32

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'None (0)'	System	28 Sep 2020 22:58:32
	System	28 Sep 2020 22:58:32

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'None (0)'	System	28 Sep 2020 22:58:32
	System	28 Sep 2020 22:58:32

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'No (N)'	System	28 Sep 2020 22:58:32
	System	28 Sep 2020 22:58:32

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered '28 Sep 2020 17:58'	System	28 Sep 2020 22:58:32
	System	28 Sep 2020 22:58:32

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' 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: 11 Aug 2021 22:55:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' 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: 11 Aug 2021 22:55:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' 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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'No (N)'	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: 11 Aug 2021 22:55:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' 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: 11 Aug 2021 22:55:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'No (N)'	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: 11 Aug 2021 22:55:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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
	System	02 Oct 2020 05:05:07

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'None (0)'	System	03 Oct 2020 02:57:57
	System	03 Oct 2020 02:57:57

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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
	System	03 Oct 2020 02:57:57

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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
	System	03 Oct 2020 02:57:57

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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
	System	03 Oct 2020 02:57:57

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'None (0)'	System	03 Oct 2020 02:57:57
	System	03 Oct 2020 02:57:57

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'None (0)'	System	03 Oct 2020 02:57:57
	System	03 Oct 2020 02:57:57

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered 'No (N)'	System	03 Oct 2020 02:57:57
	System	03 Oct 2020 02:57:57

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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' User entered '02 Oct 2020 21:57'	System	03 Oct 2020 02:57:57
	System	03 Oct 2020 02:57:57

US3552497

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:30:15
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: 11 Aug 2021 22:55:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Oct 2020 14:01:35

US3552497

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '05 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Heather Douds (b) (4)	09 Nov 2020 18:32:16
User entered '5 Oct 2020'	(b) (4)	
	Stanley Dublin (b) (4)	05 Oct 2020 14:01:35
	(b) (4)	

US3552497

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Oct 2020 14:01:35

US3552497

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Oct 2020 14:01:35

US3552497

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Oct 2020 12:30:12

US3552497

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User entered 'l'	System	13 Oct 2020 12:30:12

US3552497

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Oct 2020 12:30:21

US3552497

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '12 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Oct 2020 12:30:21

US3552497

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Oct 2020 12:30:21

US3552497

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Oct 2020 12:30:21

US3552497

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 17:10:18

US3552497

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User entered 'l'	System	19 Oct 2020 17:10:18

US3552497

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 17:10:26

US3552497

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '19 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 17:10:26

US3552497

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 17:10:26

US3552497

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 17:10:26

US3552497

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:04:56

US3552497

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User entered 'l'	System	29 Oct 2020 21:04:56

US3552497

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:57:27

US3552497

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered '29 Oct 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:57:27

US3552497

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered 'Clinic (Clinic)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:57:27

US3552497

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User entered 'VISIT2'	System	30 Oct 2020 15:57:27

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
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: 11 Aug 2021 22:55:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered 'Yes (Y)'	(b) (4) 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: 11 Aug 2021 22:55:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered '29 Oct 2020'	(b) (4) 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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered '15:30'	(b) (4) 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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
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: 11 Aug 2021 22:55:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered '99.0' F	(b) (4) 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: 11 Aug 2021 22:55:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered 'Oral (Oral)'	(b) (4) 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: 11 Aug 2021 22:55:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered empty.	(b) (4) 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: 11 Aug 2021 22:55:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered '83'	(b) (4) 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: 11 Aug 2021 22:55:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User entered 'bpm'	System	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered '22'	(b) (4) 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: 11 Aug 2021 22:55:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
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: 11 Aug 2021 22:55:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered '129'	(b) (4) 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: 11 Aug 2021 22:55:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User entered 'mmHg'	System	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered '80'	(b) (4) 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: 11 Aug 2021 22:55:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User entered 'mmHg'	System	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
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: 11 Aug 2021 22:55:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 22:55:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered empty.	(b) (4) 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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered empty.	(b) (4) 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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User entered empty.	System	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered empty.	(b) (4) 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: 11 Aug 2021 22:55:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered empty.	(b) (4) 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: 11 Aug 2021 22:55:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered empty.	(b) (4) 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: 11 Aug 2021 22:55:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered empty.	(b) (4) 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: 11 Aug 2021 22:55:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User entered empty.	System	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered empty.	(b) (4) 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: 11 Aug 2021 22:55:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User entered empty.	System	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered empty.	(b) (4) 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: 11 Aug 2021 22:55:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User entered empty.	System	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered empty.	(b) (4) 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: 11 Aug 2021 22:55:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User entered empty.	System	30 Oct 2020 15:59:08

US3552497

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:14

US3552497

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered '29 Oct 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:14

US3552497

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:30

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:26

US3552497

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:30

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered '29 Oct 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:26

US3552497

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:30

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered 'Urine (URINE)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:26

US3552497

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:30

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered 'Negative (NEGATIVE)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:26

US3552497

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:30

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:26

US3552497

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:30

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:26

US3552497

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:30

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 15:59:26

US3552497

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User entered empty.	System	30 Oct 2020 15:59:26

US3552497

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 16:00:06

US3552497

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:30

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:36:35
User closed query 'Per CDM: Primary reason indicated for dosing discontinuation in Dosing Discontinuation form is Adverse Event. Please review and update accordingly, else clarify.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 09:18:10
Query 'Per CDM: Primary reason indicated for dosing discontinuation in Dosing Discontinuation form is Adverse Event. Please review and update accordingly, else clarify.' answered with 'updated' (Site from DM).	Heather Douds (b) (4) (b) (4)	07 Jan 2021 17:30:48
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	07 Jan 2021 17:30:43
User opened query 'Per CDM: Primary reason indicated for dosing discontinuation in Dosing Discontinuation form is Adverse Event. Please review and update accordingly, else clarify.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 10:16:09
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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User closed query 'Please update the entry to specify AE - RASH TO LEFT ARM' (Site from CRA).	(b) (4)	18 Nov 2020 17:14:09
Query 'Please update the entry to specify AE - RASH TO LEFT ARM' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 16:19:36
User entered 'RASH TO LEFT ARM' reason for change: Per Query Resolution	Cassandra Zehenny (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)	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: 11 Aug 2021 22:55:30

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User entered empty.	System	30 Oct 2020 16:00:06

US3552497

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:30

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 16:00:06

US3552497

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 16:00:06

US3552497

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User entered empty.	System	30 Oct 2020 16:00:06

US3552497

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 16:00:06

US3552497

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User entered empty.	System	30 Oct 2020 16:00:06

US3552497

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:30

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User entered empty.	System	30 Oct 2020 16:00:06

US3552497

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 16:00:20

US3552497

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered '29 Oct 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 16:00:20

US3552497

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered '15:47'	(b) (4) Mikayla Frye (b) (4) (b) (4)	30 Oct 2020 16:00:20

US3552497

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
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: 11 Aug 2021 22:55:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered '29 Oct 2020'	(b) (4) 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: 11 Aug 2021 22:55:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
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: 11 Aug 2021 22:55:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered 'Yes (Y)'	(b) (4) 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: 11 Aug 2021 22:55:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered '16:12'	(b) (4) 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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
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: 11 Aug 2021 22:55:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
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: 11 Aug 2021 22:55:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 22:55:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered empty.	(b) (4) 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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User entered empty.	System	30 Oct 2020 16:00:34

US3552497

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Nov 2020 16:48:15

US3552497

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User entered 'I'	System	05 Nov 2020 16:48:15

US3552497

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Nov 2020 16:48:25

US3552497

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '05 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Heather Douds (b) (4)	09 Nov 2020 18:32:24
User entered '5 Nov 2020'	(b) (4)	
	Stanley Dublin (b) (4)	05 Nov 2020 16:48:25
	(b) (4)	

US3552497

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Nov 2020 16:48:25

US3552497

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Nov 2020 16:48:25

US3552497

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	12 Nov 2020 22:15:07

US3552497

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User entered 'l'	System	12 Nov 2020 22:15:07

US3552497

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	12 Nov 2020 22:15:16

US3552497

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '12 Nov 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	12 Nov 2020 22:15:16

US3552497

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	12 Nov 2020 22:15:16

US3552497

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	12 Nov 2020 22:15:16

US3552497

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Nov 2020 20:23:06

US3552497

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User entered 'l'	System	19 Nov 2020 20:23:06

US3552497

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Nov 2020 20:23:14

US3552497

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '19 Nov 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Nov 2020 20:23:14

US3552497

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Nov 2020 20:23:14

US3552497

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Nov 2020 20:23:14

US3552497

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Nov 2020 16:06:50

US3552497

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User entered 'l'	System	20 Nov 2020 16:06:50

US3552497

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Nov 2020 16:07:00

US3552497

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered '20 Nov 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Nov 2020 16:07:00

US3552497

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Nov 2020 16:07:00

US3552497

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User entered 'VISIT3'	System	20 Nov 2020 16:07:00

US3552497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Nov 2020 16:07:05

US3552497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Nov 2020 16:07:05

US3552497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Nov 2020 16:07:05

US3552497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User entered empty.	System	20 Nov 2020 16:07:05

US3552497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Nov 2020 16:07:05

US3552497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Nov 2020 16:07:05

US3552497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Nov 2020 16:07:05

US3552497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Nov 2020 16:07:05

US3552497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User entered empty.	System	20 Nov 2020 16:07:05

US3552497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Nov 2020 16:07:05

US3552497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User entered empty.	System	20 Nov 2020 16:07:05

US3552497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Nov 2020 16:07:05

US3552497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User entered empty.	System	20 Nov 2020 16:07:05

US3552497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Nov 2020 16:07:05

US3552497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User entered empty.	System	20 Nov 2020 16:07:05

US3552497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40

US3552497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40

US3552497

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Nov 2020 16:07:11

US3552497

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:30

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Nov 2020 16:07:11

US3552497

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Nov 2020 16:07:23

US3552497

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered '20 Nov 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Nov 2020 16:07:23

US3552497

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered '08:42'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Nov 2020 16:07:23

US3552497

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User entered '20 Nov 2020 08:42'	System	20 Nov 2020 16:07:23

US3552497

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:35
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Dec 2020 16:17:41

US3552497

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:44:40
User entered 'I'	System	18 Dec 2020 16:17:41

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-11-26T00:31:14', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '1f470748-e079-441b-bf3f-1a739b0a5004' User entered 'No (N)'	System	26 Nov 2020 06:31:23

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-11-26T00:31:16', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '1f470748-e079-441b-bf3f-1a739b0a5004'	System	26 Nov 2020 06:31:23
User entered 'No (N)'	System	26 Nov 2020 06:31:23

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-11-26T00:31:19', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '1f470748-e079-441b-bf3f-1a739b0a5004'	System	26 Nov 2020 06:31:23
User entered '26 Nov 2020 00:31:19'	System	26 Nov 2020 06:31:23

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-11-30T06:50:34', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '2242240d-ee76-4628-8925-fea35da678a5' User entered 'No (N)'	System	30 Nov 2020 12:50:40
	System	30 Nov 2020 12:50:40

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-11-30T06:50:36', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '2242240d-ee76-4628-8925-fea35da678a5' User entered 'No (N)'	System	30 Nov 2020 12:50:40

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-11-30T06:50:38', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '2242240d-ee76-4628-8925-fea35da678a5' User entered '30 Nov 2020 06:50:38'	System	30 Nov 2020 12:50:40
	System	30 Nov 2020 12:50:40

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-12-09T12:00:11', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '5514fd7a-3f16-4110-a739-f83459a98616' User entered 'No (N)'	System	09 Dec 2020 18:00:17
	System	09 Dec 2020 18:00:17

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-12-09T12:00:12', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '5514fd7a-3f16-4110-a739-f83459a98616'	System	09 Dec 2020 18:00:17
User entered 'No (N)'	System	09 Dec 2020 18:00:17

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-12-09T12:00:14', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '5514fd7a-3f16-4110-a739-f83459a98616' User entered '09 Dec 2020 12:00:14'	System	09 Dec 2020 18:00:17
	System	09 Dec 2020 18:00:17

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-12-14T00:01:12', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'd34e3412-459b-4cab-9b22-1f2c15016950'	System	14 Dec 2020 06:01:19
User entered 'No (N)'	System	14 Dec 2020 06:01:19

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-12-14T00:01:13', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'd34e3412-459b-4cab-9b22-1f2c15016950'	System	14 Dec 2020 06:01:19
User entered 'No (N)'	System	14 Dec 2020 06:01:19

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-12-14T00:01:15', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'd34e3412-459b-4cab-9b22-1f2c15016950' User entered '14 Dec 2020 00:01:15'	System	14 Dec 2020 06:01:19
	System	14 Dec 2020 06:01:19

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-12-28T00:01:11', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'e19ab765-1f82-499c-b7a0-64472474f536'	System	28 Dec 2020 06:01:19
User entered 'No (N)'	System	28 Dec 2020 06:01:19

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-12-28T00:01:13', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'e19ab765-1f82-499c-b7a0-64472474f536'	System	28 Dec 2020 06:01:19
User entered 'No (N)'	System	28 Dec 2020 06:01:19

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2020-12-28T00:01:15', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'e19ab765-1f82-499c-b7a0-64472474f536' User entered '28 Dec 2020 00:01:15'	System	28 Dec 2020 06:01:19
	System	28 Dec 2020 06:01:19

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-01-08T12:57:43', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'b43ad002-02f5-4340-be90-f67066fa3ab9' User entered 'No (N)'	System	08 Jan 2021 18:57:52
	System	08 Jan 2021 18:57:52

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-01-08T12:57:45', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'b43ad002-02f5-4340-be90-f67066fa3ab9' User entered 'No (N)'	System	08 Jan 2021 18:57:52

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-01-08T12:57:47', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'b43ad002-02f5-4340-be90-f67066fa3ab9' User entered '08 Jan 2021 12:57:47'	System	08 Jan 2021 18:57:52
	System	08 Jan 2021 18:57:52

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-01-13T23:50:48', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '025c01c9-0f46-49a9-be38-2a45929e217f' User entered 'No (N)'	System	14 Jan 2021 05:50:56
	System	14 Jan 2021 05:50:56

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-01-13T23:50:52', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '025c01c9-0f46-49a9-be38-2a45929e217f' User entered 'No (N)'	System	14 Jan 2021 05:50:56

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-01-13T23:50:53', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '025c01c9-0f46-49a9-be38-2a45929e217f' User entered '13 Jan 2021 23:50:53'	System	14 Jan 2021 05:50:56
	System	14 Jan 2021 05:50:56

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-01-21T09:49:03', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'f8f24d42-ba3d-4188-9ed1-b30a434b62cb' User entered 'No (N)'	System	21 Jan 2021 15:49:19
	System	21 Jan 2021 15:49:19

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-01-21T09:49:06', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'f8f24d42-ba3d-4188-9ed1-b30a434b62cb' User entered 'No (N)'	System	21 Jan 2021 15:49:19

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-01-21T09:49:08', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'f8f24d42-ba3d-4188-9ed1-b30a434b62cb' User entered '21 Jan 2021 09:49:08'	System	21 Jan 2021 15:49:19
	System	21 Jan 2021 15:49:19

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-01-25T00:11:42', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '971bbef5-7f29-4995-ba29-701ca56ad035'	System	25 Jan 2021 06:11:48
User entered 'No (N)'	System	25 Jan 2021 06:11:48

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-01-25T00:11:44', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '971bbef5-7f29-4995-ba29-701ca56ad035'	System	25 Jan 2021 06:11:48
User entered 'No (N)'	System	25 Jan 2021 06:11:48

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-01-25T00:11:46', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '971bbef5-7f29-4995-ba29-701ca56ad035' User entered '25 Jan 2021 00:11:46'	System	25 Jan 2021 06:11:48
	System	25 Jan 2021 06:11:48

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-02-01T00:02:03', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'fb88ce0a-12bf-439e-9326-28d3ea912cbc'	System	01 Feb 2021 06:02:09
User entered 'No (N)'	System	01 Feb 2021 06:02:09

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-02-01T00:02:04', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'fb88ce0a-12bf-439e-9326-28d3ea912cbc'	System	01 Feb 2021 06:02:09
User entered 'No (N)'	System	01 Feb 2021 06:02:09

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-02-01T00:02:06', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'fb88ce0a-12bf-439e-9326-28d3ea912cbc'	System	01 Feb 2021 06:02:09
User entered '01 Feb 2021 00:02:06'	System	01 Feb 2021 06:02:09

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-02-12T14:49:05', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '59ddbcba-130a-44a1-9f75-8ad400d3f1e5' User entered 'No (N)'	System	12 Feb 2021 20:49:23
	System	12 Feb 2021 20:49:23

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-02-12T14:49:16', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '59ddbcba-130a-44a1-9f75-8ad400d3f1e5' User entered 'No (N)'	System	12 Feb 2021 20:49:23

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-02-12T14:49:18', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '59ddbcba-130a-44a1-9f75-8ad400d3f1e5' User entered '12 Feb 2021 14:49:18'	System	12 Feb 2021 20:49:23
	System	12 Feb 2021 20:49:23

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-02-15T00:01:29', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'c18edd85-3657-4e18-b989-fbe2d1813c3b' User entered 'No (N)'	System	15 Feb 2021 06:01:40
	System	15 Feb 2021 06:01:40

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-02-15T00:01:31', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'c18edd85-3657-4e18-b989-fbe2d1813c3b' User entered 'No (N)'	System	15 Feb 2021 06:01:40
	System	15 Feb 2021 06:01:40

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-02-15T00:01:35', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'c18edd85-3657-4e18-b989-fbe2d1813c3b' User entered '15 Feb 2021 00:01:35'	System	15 Feb 2021 06:01:40
	System	15 Feb 2021 06:01:40

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-02-25T16:38:38-06:00', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'c2c88ebd-a9dc-436a-8b2a-e60d7816af41' User entered 'No (N)'	System	25 Feb 2021 22:38:45
	System	25 Feb 2021 22:38:45

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-02-25T16:38:39-06:00', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'c2c88ebd-a9dc-436a-8b2a-e60d7816af41' User entered 'No (N)'	System	25 Feb 2021 22:38:45

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-02-25T16:38:41-06:00', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'c2c88ebd-a9dc-436a-8b2a-e60d7816af41' User entered '25 Feb 2021 22:38:41'	System	25 Feb 2021 22:38:45
	System	25 Feb 2021 22:38:45

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-03-03T17:57:38-06:00', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'd9bd0779-6ba0-4ef9-a14f-7309eafa810e'	System	03 Mar 2021 23:57:46
User entered 'No (N)'	System	03 Mar 2021 23:57:46

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-03-03T17:57:40-06:00', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'd9bd0779-6ba0-4ef9-a14f-7309eafa810e'	System	03 Mar 2021 23:57:46
User entered 'No (N)'	System	03 Mar 2021 23:57:46

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-03-03T17:57:42-06:00', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'd9bd0779-6ba0-4ef9-a14f-7309eafa810e' User entered '03 Mar 2021 17:57:42'	System	03 Mar 2021 23:57:46
	System	03 Mar 2021 23:57:46

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-03-12T11:21:57-06:00', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'edf2fed4-8cbf-441b-8fbf-d833f3329c79'	System	12 Mar 2021 17:22:04
User entered 'No (N)'	System	12 Mar 2021 17:22:04

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-03-12T11:22:00-06:00', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'edf2fed4-8cbf-441b-8fbf-d833f3329c79'	System	12 Mar 2021 17:22:04
User entered 'No (N)'	System	12 Mar 2021 17:22:04

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-03-12T11:22:02-06:00', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'edf2fed4-8cbf-441b-8fbf-d833f3329c79'	System	12 Mar 2021 17:22:04
User entered '12 Mar 2021 11:22:02'	System	12 Mar 2021 17:22:04

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-03-19T15:11:26-05:00', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'ee631d73-c1a5-474f-b8ff-da24d99f017c'	System	19 Mar 2021 20:11:35
User entered 'No (N)'	System	19 Mar 2021 20:11:35

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-03-19T15:11:28-05:00', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'ee631d73-c1a5-474f-b8ff-da24d99f017c' User entered 'No (N)'	System	19 Mar 2021 20:11:35

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-03-19T15:11:30-05:00', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'ee631d73-c1a5-474f-b8ff-da24d99f017c' User entered '19 Mar 2021 15:11:30'	System	19 Mar 2021 20:11:35
	System	19 Mar 2021 20:11:35

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-03-22T00:19:01-05:00', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '72149394-030a-4a60-8e0e-9088a52a1dc0'	System	22 Mar 2021 05:19:09
User entered 'No (N)'	System	22 Mar 2021 05:19:09

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-03-22T00:19:03-05:00', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '72149394-030a-4a60-8e0e-9088a52a1dc0'	System	22 Mar 2021 05:19:09
User entered 'No (N)'	System	22 Mar 2021 05:19:09

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-03-22T00:19:06-05:00', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '72149394-030a-4a60-8e0e-9088a52a1dc0'	System	22 Mar 2021 05:19:09
User entered '22 Mar 2021 00:19:06'	System	22 Mar 2021 05:19:09

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-03-29T01:37:39-05:00', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '7712903a-403f-4db8-a0f1-9da4960c1c7f' User entered 'No (N)'	System	29 Mar 2021 06:38:10
	System	29 Mar 2021 06:38:10

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-03-29T01:37:42-05:00', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '7712903a-403f-4db8-a0f1-9da4960c1c7f'	System	29 Mar 2021 06:38:10
User entered 'No (N)'	System	29 Mar 2021 06:38:10

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-03-29T01:38:04-05:00', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '7712903a-403f-4db8-a0f1-9da4960c1c7f' User entered '29 Mar 2021 01:38:04'	System	29 Mar 2021 06:38:10
	System	29 Mar 2021 06:38:10

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-04-07T12:39:34-05:00', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '1e27d879-df0c-45fb-94f8-d55be6d62f89'	System	07 Apr 2021 17:39:40
User entered 'No (N)'	System	07 Apr 2021 17:39:40

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-04-07T12:39:35-05:00', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '1e27d879-df0c-45fb-94f8-d55be6d62f89'	System	07 Apr 2021 17:39:40
User entered 'No (N)'	System	07 Apr 2021 17:39:40

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-04-07T12:39:37-05:00', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '1e27d879-df0c-45fb-94f8-d55be6d62f89'	System	07 Apr 2021 17:39:40
User entered '07 Apr 2021 12:39:37'	System	07 Apr 2021 17:39:40

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-04-15T18:13:02-05:00', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '29bb18d1-4ba7-452e-b8f2-dc72ba7fb11b' User entered 'No (N)'	System	15 Apr 2021 23:13:09
	System	15 Apr 2021 23:13:09

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-04-15T18:13:04-05:00', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '29bb18d1-4ba7-452e-b8f2-dc72ba7fb11b' User entered 'No (N)'	System	15 Apr 2021 23:13:09
	System	15 Apr 2021 23:13:09

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-04-15T18:13:06-05:00', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '29bb18d1-4ba7-452e-b8f2-dc72ba7fb11b'	System	15 Apr 2021 23:13:09
User entered '15 Apr 2021 18:13:06'	System	15 Apr 2021 23:13:09

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-04-19T00:03:51-05:00', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '0d6541ef-0419-4318-9c1a-094570d877fc' User entered 'No (N)'	System	19 Apr 2021 05:03:56
	System	19 Apr 2021 05:03:56

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-04-19T00:03:52-05:00', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '0d6541ef-0419-4318-9c1a-094570d877fc' User entered 'No (N)'	System	19 Apr 2021 05:03:56
	System	19 Apr 2021 05:03:56

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-04-19T00:03:54-05:00', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: '0d6541ef-0419-4318-9c1a-094570d877fc' User entered '19 Apr 2021 00:03:54'	System	19 Apr 2021 05:03:56
	System	19 Apr 2021 05:03:56

US3552497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:55:30

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:47:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-03-03T17:57:34-06:00', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'd7c3d5a5-686e-4518-9d94-54ea88af3578'	System	03 Mar 2021 23:57:40
User entered 'No (N)'	System	03 Mar 2021 23:57:40

US3552497

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:55:30

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:47:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D37406C4-A942-445B-8C29-A99D022CB245)', Time: '2021-03-03T17:57:36-06:00', User OID: 'PatientReportedOutcome (US3552497)', ODM File OID: 'd7c3d5a5-686e-4518-9d94-54ea88af3578' User entered '03 Mar 2021 17:57:36'	System	03 Mar 2021 23:57:40
	System	03 Mar 2021 23:57:40

US3552497

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Dec 2020 16:18:15

US3552497

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '18 Dec 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Dec 2020 16:18:15

US3552497

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4)	18 Dec 2020 16:18:15

US3552497

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	18 Dec 2020 16:18:15

US3552497

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 16:27:33

US3552497

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:06:11
User entered 'l'	System	21 Jan 2021 16:27:33

US3552497

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:15:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 16:27:45

US3552497

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:15:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '21 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 16:27:45

US3552497

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:15:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 16:27:45

US3552497

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:15:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 16:27:45

US3552497

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:15:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Cassandra Zehenny (b) (4)	11 Feb 2021 21:17:08

US3552497

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:15:37
User entered 'l'	System	11 Feb 2021 21:17:08

US3552497

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:15:37
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:32:34
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 18:06:57

US3552497

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:15:37
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:32:34
User entered '22 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 18:06:57

US3552497

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:15:37
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:32:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 18:06:57

US3552497

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:15:37
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:32:34
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 18:06:57

US3552497

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:15:37
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:32:34
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 18:07:01

US3552497

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:15:37
User entered 'l'	System	22 Feb 2021 18:07:01

US3552497

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:31:33
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:44:41
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	22 Mar 2021 19:13:42

US3552497

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:31:33
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:44:41
User entered '22 Mar 2021'	Heather Douds (b) (4) (b) (4)	22 Mar 2021 19:13:42

US3552497

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:31:33
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:44:41
User entered 'Contact Made (CONTACT MADE)'	Heather Douds (b) (4) (b) (4)	22 Mar 2021 19:13:42

US3552497

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:31:33
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:44:41
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	22 Mar 2021 19:13:42

US3552497

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:31:33
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:04:58
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Apr 2021 18:16:30

US3552497

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:31:33
User entered 'l'	System	13 Apr 2021 18:16:30

US3552497

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:05:01
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Apr 2021 18:19:17

US3552497

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:05:01
User entered '13 Apr 2021'	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Apr 2021 18:19:17

US3552497

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:05:01
User entered 'Clinic (Clinic)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Apr 2021 18:19:17

US3552497

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:30

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	13 Apr 2021 18:19:17

US3552497

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:05:01
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Apr 2021 18:19:21

US3552497

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:05:01
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Apr 2021 18:19:21

US3552497

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:05:01
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Apr 2021 18:19:21

US3552497

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 18:19:21

US3552497

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:05:01
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Apr 2021 18:19:21

US3552497

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:05:01
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Apr 2021 18:19:21

US3552497

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:05:01
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Apr 2021 18:19:21

US3552497

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:05:01
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Apr 2021 18:19:21

US3552497

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 18:19:21

US3552497

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:05:01
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Apr 2021 18:19:21

US3552497

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 18:19:21

US3552497

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:05:01
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Apr 2021 18:19:21

US3552497

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 18:19:21

US3552497

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:05:01
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Apr 2021 18:19:21

US3552497

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 18:19:21

US3552497

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:04:58
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Apr 2021 18:19:24

US3552497

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:30

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:04:58
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Apr 2021 18:19:24

US3552497

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:04:58
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Apr 2021 18:19:32

US3552497

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:04:58
User entered '13 Apr 2021'	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Apr 2021 18:19:32

US3552497

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:04:58
User entered '12:38'	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Apr 2021 18:19:32

US3552497

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
User entered '13 Apr 2021 12:38'	System	13 Apr 2021 18:19:32

US3552497

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:04:58
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Apr 2021 18:19:36

US3552497

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:30

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 18:19:36

US3552497

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

Form: Visit Date

Generated On: 11 Aug 2021 22:55:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:35:33

US3552497

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

Form: Visit Date

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '20 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:35:33

US3552497

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

Form: Visit Date

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:35:33

US3552497

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

Form: Visit Date

Generated On: 11 Aug 2021 22:55:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered 'UNBLND_DECIDE'	System	20 Jan 2021 20:35:33

US3552497

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:30

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '20 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:37:27

US3552497

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:30

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:44:41
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 20:02:38

US3552497

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:30

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:37:27

US3552497

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:30

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:44:41
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 20:02:38

US3552497

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:30

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '20 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:37:27

US3552497

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:30

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Stanley Doublin (b) (4)	20 Jan 2021 20:37:27

US3552497

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:30

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Stanley Doublin (b) (4)	20 Jan 2021 20:37:27

US3552497

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:30

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Not Administered (NA)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:37:27

US3552497

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:30

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:37:27

US3552497

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:30

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered empty.	System	20 Jan 2021 20:37:27

US3552497

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:30

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered 'I'	System	20 Jan 2021 20:37:27

US3552497

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered missing code ND - Not Done.	(b) (4) Stanley Doublin (b) (4) (b) (4)	20 Jan 2021 20:38:08

US3552497

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:38:08

US3552497

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered empty.	System	20 Jan 2021 20:38:08
DataPoint set to visible.	System	20 Jan 2021 20:37:27

US3552497

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4)	20 Jan 2021 20:38:08

US3552497

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:38:08

US3552497

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered empty.	System	20 Jan 2021 20:38:08
DataPoint set to visible.	System	20 Jan 2021 20:37:27

US3552497

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	20 Jan 2021 20:38:08

US3552497

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:38:08

US3552497

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '20 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:38:08

US3552497

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '13:10'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:38:08

US3552497

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered '20 Jan 2021 13:10'	System	20 Jan 2021 20:38:08

US3552497

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '98.8' F	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:38:08

US3552497

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Oral (Oral)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:38:08

US3552497

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:38:08

US3552497

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '66'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:38:08

US3552497

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered 'bpm'	System	20 Jan 2021 20:38:08

US3552497

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '16'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:38:08

US3552497

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered 'breaths/min'	System	20 Jan 2021 20:38:08

US3552497

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '108'	(b) (4) Stanley Doublin (b) (4) (b) (4)	20 Jan 2021 20:38:08

US3552497

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered 'mmHg'	System	20 Jan 2021 20:38:08

US3552497

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '67'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:38:08

US3552497

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered 'mmHg'	System	20 Jan 2021 20:38:08

US3552497

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:38:08

US3552497

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:38:08

US3552497

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered empty.	System	20 Jan 2021 20:38:08
DataPoint set to visible.	System	20 Jan 2021 20:37:27

US3552497

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	20 Jan 2021 20:38:30

US3552497

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:38:30

US3552497

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '20 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:38:30

US3552497

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '14:06'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:38:30

US3552497

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered '20 Jan 2021 14:06'	System	20 Jan 2021 20:38:30

US3552497

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '98.9' F	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:38:30

US3552497

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Oral (Oral)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:38:30

US3552497

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:38:30

US3552497

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '66'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:38:30

US3552497

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered 'bpm'	System	20 Jan 2021 20:38:30

US3552497

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '16'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:38:30

US3552497

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered 'breaths/min'	System	20 Jan 2021 20:38:30

US3552497

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '121'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:38:30

US3552497

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered 'mmHg'	System	20 Jan 2021 20:38:30

US3552497

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '66'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:38:30

US3552497

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered 'mmHg'	System	20 Jan 2021 20:38:30

US3552497

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:38:40

US3552497

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:30

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '20 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:38:40

US3552497

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:30

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:38:55

US3552497

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:30

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '20 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:38:55

US3552497

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:30

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Urine (URINE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:38:55

US3552497

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:30

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Negative (NEGATIVE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:38:55

US3552497

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:30

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:38:55

US3552497

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:30

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '20 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:38:55

US3552497

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:30

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '13:25'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:38:55

US3552497

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered '20 Jan 2021 13:25'	System	20 Jan 2021 20:38:55

US3552497

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

Form: Exposure

Generated On: 11 Aug 2021 22:55:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:39:11

US3552497

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

Form: Exposure

Generated On: 11 Aug 2021 22:55:30

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:39:11

US3552497

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

Form: Exposure

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:39:11

US3552497

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

Form: Exposure

Generated On: 11 Aug 2021 22:55:30

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered 'mRNA-1273'	System	20 Jan 2021 20:39:11
DataPoint set to visible.	System	20 Jan 2021 20:37:27

US3552497

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

Form: Exposure

Generated On: 11 Aug 2021 22:55:30

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '20 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:39:11

US3552497

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

Form: Exposure

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '13:36'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:39:11

US3552497

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

Form: Exposure

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered '20 Jan 2021 13:36'	System	20 Jan 2021 20:39:11

US3552497

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

Form: Exposure

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:39:11

US3552497

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

Form: Exposure

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered 'ONCE'	System	20 Jan 2021 20:39:11

US3552497

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

Form: Exposure

Generated On: 11 Aug 2021 22:55:30

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered 'INTRAMUSCULAR'	System	20 Jan 2021 20:39:11

US3552497

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:39:21

US3552497

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '20 Jan 2021'	(b) (4) Stanley Dublin (b) (4)	20 Jan 2021 20:39:21

US3552497

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '12:57'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:39:21

US3552497

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered '20 Jan 2021 12:57'	System	20 Jan 2021 20:39:21

US3552497

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:55:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4)	20 Jan 2021 20:39:30

US3552497

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:55:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '20 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:39:30

US3552497

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '13:00'	(b) (4) Stanley Dublin (b) (4) (b) (4)	20 Jan 2021 20:39:30

US3552497

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered '20 Jan 2021 13:00'	System	20 Jan 2021 20:39:30

US3552497

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

Form: Continuing

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	27 Jan 2021 19:33:14

US3552497

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

Form: Continuing

Generated On: 11 Aug 2021 22:55:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:49
User entered 'I'	System	27 Jan 2021 19:33:14

US3552497

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	27 Jan 2021 19:33:23

US3552497

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '27 Jan 2021'	(b) (4) Mikayla Frye (b) (4) (b) (4)	27 Jan 2021 19:33:23

US3552497

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	27 Jan 2021 19:33:23

US3552497

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	27 Jan 2021 19:33:23

US3552497

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	11 Feb 2021 21:17:15

US3552497

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:56
User entered 'l'	System	11 Feb 2021 21:17:15

US3552497

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:30

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:56
User entered 'I'	System	11 Feb 2021 21:17:15
DataPoint set to visible.	System	11 Feb 2021 21:17:15

US3552497

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:03
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:32:34
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Feb 2021 18:43:47

US3552497

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:03
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:32:34
User entered '24 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Feb 2021 18:43:47

US3552497

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:03
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:32:34
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Feb 2021 18:43:47

US3552497

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:03
User entered 'OLD29'	System	24 Feb 2021 18:43:47

US3552497

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:03
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:32:34
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Feb 2021 18:45:34

US3552497

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:03
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:32:34
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Feb 2021 18:45:34

US3552497

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:03
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:32:34
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Feb 2021 18:45:34

US3552497

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:03
User entered empty.	System	24 Feb 2021 18:45:34

US3552497

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:03
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:32:34
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Feb 2021 18:45:34

US3552497

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:03
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:32:34
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Feb 2021 18:45:34

US3552497

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:03
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:32:34
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Feb 2021 18:45:34

US3552497

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:03
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:32:34
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Feb 2021 18:45:34

US3552497

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:03
User entered empty.	System	24 Feb 2021 18:45:34

US3552497

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:03
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:32:34
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Feb 2021 18:45:34

US3552497

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:03
User entered empty.	System	24 Feb 2021 18:45:34

US3552497

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:03
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:32:34
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Feb 2021 18:45:34

US3552497

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:03
User entered empty.	System	24 Feb 2021 18:45:34

US3552497

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:03
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:32:34
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Feb 2021 18:45:34

US3552497

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:03
User entered empty.	System	24 Feb 2021 18:45:34

US3552497

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:03

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Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:30

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:03

US3552497

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:03
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:32:34
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Feb 2021 18:45:44

US3552497

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:30

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:03
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:32:34
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Feb 2021 18:45:44

US3552497

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:03
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:32:34
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Feb 2021 18:45:54

US3552497

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:03
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:32:34
User entered '24 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Feb 2021 18:45:54

US3552497

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:03
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:32:34
User entered '10:46'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Feb 2021 18:45:54

US3552497

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:03
User entered '24 Feb 2021 10:46'	System	24 Feb 2021 18:45:54

US3552497

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:55:30

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:39:25
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 17:29:33

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:30

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site urticaria, LLT: Urticaria injection site - version MedDRA\23.0.	Coder Import (b) (4)	19 Jan 2021 16:52:08
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	19 Jan 2021 16:52:08
User closed query 'Per DM CLR: Please review AE and please update to specify if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 09:12:50
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site rash, LLT: Injection site rash - version MedDRA\23.0.	Coder Import (b) (4)	30 Dec 2020 17:07:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	30 Dec 2020 17:07:17
Data point term sent to Coder	System	30 Dec 2020 16:38:46
Query 'Per DM CLR: Please review AE and please update to specify if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify. ' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	30 Dec 2020 16:38:11
Coding entries removed.	Cassandra Zehenny (b) (4)	30 Dec 2020 16:38:03
User entered 'urticarial INJECTION SITE RASH TO LEFT ARM' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	30 Dec 2020 16:38:03
User opened query 'Per DM CLR: Please review AE and please update to specify if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	26 Dec 2020 22:09:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:30

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site rash, LLT: Injection site rash - version MedDRA\23.0.	Coder Import (b) (4)	03 Dec 2020 07:48:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	03 Dec 2020 07:48:56
User closed query 'Per MM : to help clarify the clinical significance of the event and possible association with the administration of investigational product and/or study procedure, if this event is related to the site of administration, please update the Adverse Event to "Injection site rash left arm." Thank You.	(b) (4), (b) (6)	03 Dec 2020 05:23:49
' (Site from DM).		
Data point term sent to Coder	System	01 Dec 2020 17:55:17
Query 'Per MM : to help clarify the clinical significance of the event and possible association with the administration of investigational product and/or study procedure, if this event is related to the site of administration, please update the Adverse Event to "Injection site rash left arm." Thank You.	Cassandra Zehenny (b) (4)	01 Dec 2020 17:54:41
' answered with 'updated per query request' (Site from DM).		
Coding entries removed.	Cassandra Zehenny (b) (4)	01 Dec 2020 17:54:32
User entered 'injection site RASH TO LEFT ARM' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	01 Dec 2020 17:54:32
User opened query 'Per MM : to help clarify the clinical significance of the event and possible association with the administration of investigational product and/or study procedure, if this event is related to the site of administration, please update the Adverse Event to "Injection site rash left arm." Thank You.	(b) (4), (b) (6)	01 Dec 2020 08:53:01
' (Site from DM).		
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)	30 Oct 2020 22:19:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:30

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. Data point term sent to Coder	Coder Import (b) (4)	30 Oct 2020 22:19:03
User entered 'rash to left arm'	System	30 Oct 2020 17:30:30
	Stanley Doublin (b) (4)	30 Oct 2020 17:30:20
	(b) (4)	

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:30

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:30

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:30

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '03 Oct 2020' reason for change: Data Entry Error	(b) (4) Heather Douds (b) (4)	09 Nov 2020 18:32:44
User entered '3 Oct 2020'	(b) (4) Stanley Doublin (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:30

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:30

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '06 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	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).	(b) (4)	
	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 Doublin (b) (4)	30 Oct 2020 17:30:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:30

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:30

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 17:30:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:30

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:30

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:30

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:30

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:30

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:30

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:30

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:30

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Related (RELATED)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:30

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Related (RELATED)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

US3552497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:30

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:30

None

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'l'	(b) (4) Stanley Doublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:30

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:30

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:30

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4)	
	Stanley Doublin (b) (4)	30 Oct 2020 17:30:42
	(b) (4)	
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 Doublin (b) (4)	30 Oct 2020 17:30:28
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 17:30:20
User entered empty.	Stanley Doublin (b) (4)	30 Oct 2020 17:30:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:30

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:30

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	30 Oct 2020 17:30:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:30

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	30 Oct 2020 17:30:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:30

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Oct 2020 17:30:20

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:55:30

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:39:25
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 12:17:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:30

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
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)	30 Nov 2020 20:19:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Nov 2020 20:19:57
Data point term sent to Coder	System	30 Nov 2020 20:19:07
Coding entries removed.	Cassandra Zehenny (b) (4)	30 Nov 2020 20:18:40
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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:30

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'lilletta IUD'	Stanley Dublin (b) (4)	28 Sep 2020 12:18:44
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:18:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'birth control'	(b) (4) Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:18:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) 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 Doublin (b) (4) (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) (b) (4)	28 Sep 2020 12:18:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) 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) (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) (b) (4)	28 Sep 2020 12:18:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:18:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User closed query 'Per DM CLR: Please review frequency as this was not given once per ongoing dates. Either update frequency or provide end date. Else, clarify. ' (Site from DM). Query 'Per DM CLR: Please review frequency as this was not given once per ongoing dates. Either update frequency or provide end date. Else, clarify. ' answered with 'updated' (Site from DM). User entered 'other (OTHER)' reason for change: Data Entry Error User opened query 'Per DM CLR: Please review frequency as this was not given once per ongoing dates. Either update frequency or provide end date. Else, clarify. ' (Site from DM). User closed query 'Data is required. Please complete.' (Site from System). Query 'Data is required. Please complete.' answered by data change (Site from System). User entered 'once (ONCE)' reason for change: Data Entry Error User opened query 'Data is required. Please complete.' (Site from System). User entered empty.	(b) (4) (b) (4), (b) (6) Cassandra Zehenny (b) (4) (b) (4) Cassandra Zehenny (b) (4) (b) (4) (b) (4), (b) (6) System System Stanley Doublin (b) (4) (b) (4) System Stanley Doublin (b) (4) (b) (4)	02 Dec 2020 05:41:37 30 Nov 2020 20:18:47 30 Nov 2020 20:18:40 27 Nov 2020 02:07:48 29 Sep 2020 17:33:24 29 Sep 2020 17:33:24 29 Sep 2020 17:33:24 28 Sep 2020 12:18:44 28 Sep 2020 12:18:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User closed query 'Per DM CLR: Please review the recorded Frequency as this is not expected for this medication. Please determine how much time the device is left in place before it is removed or replaced; update to reflect this as the frequency for the medication. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Please review the recorded Frequency as this is not expected for this medication. Please determine how much time the device is left in place before it is removed or replaced; update to reflect this as the frequency for the medication. Otherwise, clarify.' answered with 'continuous until ended' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 11:10:46
User opened query 'Per DM CLR: Please review the recorded Frequency as this is not expected for this medication. Please determine how much time the device is left in place before it is removed or replaced; update to reflect this as the frequency for the medication. Otherwise, clarify.' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	28 Jan 2021 20:46:54
User entered 'continuous' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Jan 2021 04:51:03
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	30 Nov 2020 20:18:40
	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:18:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4) Cassandra Zehenny (b) (4)	30 Nov 2020 20:18:40
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 Doublin (b) (4) (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) (b) (4)	28 Sep 2020 12:18:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'intrauterine' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Nov 2020 20:18:40
User entered empty.	(b) (4)	
	Stanley Doublin (b) (4)	28 Sep 2020 12:18:44
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'un UNK 2017'	(b) (4) Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:18:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) 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: 11 Aug 2021 22:55:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:18:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:18:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 12:18:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
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.	(b) (4) 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: 11 Aug 2021 22:55:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 22:55:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'hypothyroidism'	(b) (4) 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: 11 Aug 2021 22:55:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '175/150'	(b) (4) 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: 11 Aug 2021 22:55:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'mg (mg)'	(b) (4) 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: 11 Aug 2021 22:55:30

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) 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: 11 Aug 2021 22:55:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'once daily (QD)'	(b) (4) 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: 11 Aug 2021 22:55:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) 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: 11 Aug 2021 22:55:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Oral (ORAL)'	(b) (4) 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: 11 Aug 2021 22:55:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) 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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'un UNK 2016'	(b) (4) 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: 11 Aug 2021 22:55:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) 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: 11 Aug 2021 22:55:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) 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: 11 Aug 2021 22:55:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) 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: 11 Aug 2021 22:55:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 22:55:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	28 Sep 2020 12:20:21

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Sep 2020 12:20:21

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
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.	(b) (4) 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 Doublin (b) (4)	28 Sep 2020 12:22:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
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). 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).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 05:55:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Mikayla Frye (b) (4) (b) (4)	11 Nov 2020 16:11:48
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). 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). 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).	Mikayla Frye (b) (4) (b) (4) (b) (4), (b) (6)	11 Nov 2020 16:11:45 11 Nov 2020 14:49:20 11 Nov 2020 14:49:20
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. ' 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 entered 'No (N)'	(b) (4), (b) (6) Stanley Doublin (b) (4) (b) (4)	02 Nov 2020 05:32:34 28 Sep 2020 12:22:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'health promotion'	(b) (4) 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: 11 Aug 2021 22:55:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
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) (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) (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.		02 Nov 2020 05:32:21
Data hard locked.		02 Nov 2020 05:32:18
User entered 'I'	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: 11 Aug 2021 22:55:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'tablet (TABLET)'	(b) (4) 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: 11 Aug 2021 22:55:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) 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: 11 Aug 2021 22:55:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'once daily (QD)'	(b) (4) 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: 11 Aug 2021 22:55:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) 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: 11 Aug 2021 22:55:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Oral (ORAL)'	(b) (4) 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: 11 Aug 2021 22:55:30

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) 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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'un UNK 2015'	(b) (4) 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: 11 Aug 2021 22:55:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) 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: 11 Aug 2021 22:55:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) 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: 11 Aug 2021 22:55:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) 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: 11 Aug 2021 22:55:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 22:55:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	28 Sep 2020 12:22:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	28 Sep 2020 12:22:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
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.	(b) (4) 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: 11 Aug 2021 22:55:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
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)	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).		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 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: 11 Aug 2021 22:55:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'health promotion'	(b) (4) 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: 11 Aug 2021 22:55:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User closed query 'Per DM CLR: Please confirm in this query if actual dose for this medication is unknown. Else, provide the actual dose instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM). Query 'Per DM CLR: Please confirm in this query if actual dose for this medication is unknown. Else, provide the actual dose instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'Subject reported data, exact dosage unknown. Thank you.' (Site from DM). User opened query 'Per DM CLR: Please confirm in this query if actual dose for this medication is unknown. Else, provide the actual dose instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM). Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' canceled (Site from DM). User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM). 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) (4), (b) (6) Cassandra Zehenny (b) (4) (b) (4) (b) (4), (b) (6)	21 Jan 2021 05:03:10 19 Jan 2021 20:11:58 19 Jan 2021 05:48:11 19 Jan 2021 05:47:17 19 Jan 2021 05:45:12 03 Nov 2020 07:36:41

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:30

[Dose per administration](#)

Audit	User	Time (GMT)
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). 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). User entered 'I'	Cassandra Zehenny (b) (4)	02 Nov 2020 15:39:39
	(b) (4), (b) (6)	02 Nov 2020 05:33:46
	Stanley Doublin (b) (4)	28 Sep 2020 12:23:16
	(b) (4)	

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'tablet (TABLET)'	(b) (4) 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: 11 Aug 2021 22:55:30

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) 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: 11 Aug 2021 22:55:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'once daily (QD)'	(b) (4) 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: 11 Aug 2021 22:55:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) 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: 11 Aug 2021 22:55:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Oral (ORAL)'	(b) (4) 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: 11 Aug 2021 22:55:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) 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: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'un May 2020'	(b) (4) 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: 11 Aug 2021 22:55:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) 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: 11 Aug 2021 22:55:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) 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: 11 Aug 2021 22:55:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) 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: 11 Aug 2021 22:55:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 22:55:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	28 Sep 2020 12:23:16

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Sep 2020 12:23:16

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:30

[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: 11 Aug 2021 22:55:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
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)	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)	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)	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)	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)	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)	19 Oct 2020 17:24:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:55:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Yes (Y)'	(b) (4) 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: 11 Aug 2021 22:55:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'INFLUENZA PROPHYLAXIS'	(b) (4)	
reason for change: Data Entry Error	Stanley Dublin (b) (4)	20 Nov 2020 16:08:14
User entered 'prophylaxis'	(b) (4)	
	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: 11 Aug 2021 22:55:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:41
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 19:36:14
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 10:12:55
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	30 Nov 2020 20:19:17
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 02:07:20
User entered 'I'	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: 11 Aug 2021 22:55:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Other (OTHER)'	(b) (4) 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: 11 Aug 2021 22:55:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'injection' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Nov 2020 20:19:13
User entered 'cc'	(b) (4)	
	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: 11 Aug 2021 22:55:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'once (ONCE)'	(b) (4) 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: 11 Aug 2021 22:55:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) 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: 11 Aug 2021 22:55:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) 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: 11 Aug 2021 22:55:30

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) 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: 11 Aug 2021 22:55:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '13 Oct 2020'	(b) (4) 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: 11 Aug 2021 22:55:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) 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: 11 Aug 2021 22:55:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 22:55:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '13 Oct 2020'	(b) (4) 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: 11 Aug 2021 22:55:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 22:55:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:41
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: 11 Aug 2021 22:55:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:41
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: 11 Aug 2021 22:55:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:41
User entered empty.	System	19 Oct 2020 17:24:47

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Jan 2021 00:35:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Jan 2021 00:35:13
Data point term sent to Coder	System	21 Jan 2021 16:29:21
User entered 'ibuprofen'	Stanley Doublin (b) (4)	21 Jan 2021 16:29:12

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4)	21 Jan 2021 16:29:12

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:45
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.		25 Feb 2021 06:19:37
' (Site from DM).		
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.	Cassandra Zehenny (b) (4)	23 Feb 2021 15:54:41
' answered with 'ARs not AEs' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.	(b) (4), (b) (6)	23 Feb 2021 08:13:51
' (Site from DM).		
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
	(b) (4)	
User entered 'pain at injection site, fever, chills, body aches'	Stanley Doublin (b) (4)	21 Jan 2021 16:29:12
	(b) (4)	

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '600'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 16:29:12

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'mg (mg)'	(b) (4) Stanley Dublin (b) (4)	21 Jan 2021 16:29:12

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) Stanley Dublin (b) (4)	21 Jan 2021 16:29:12

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'once (ONCE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 16:29:12

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 16:29:12

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'Oral (ORAL)'	(b) (4) Stanley Dublin (b) (4)	21 Jan 2021 16:29:12

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:30

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 16:29:12

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '21 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 16:29:12

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 16:29:12

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4)	21 Jan 2021 16:29:12

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered '21 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 16:29:12

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:36:14
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 16:29:12

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:45
User entered empty.	System	21 Jan 2021 16:29:12

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:45
User entered empty.	System	21 Jan 2021 16:29:12

US3552497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:45
User entered empty.	System	21 Jan 2021 16:29:12

US3552497

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:55:30

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:32:34
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	22 Feb 2021 18:07:09

US3552497

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:55:30

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:32:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:36:14
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: 11 Aug 2021 22:55:30

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:32:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:36:14
User entered 'AE (specify) (ADVERSE EVENT)'	Heather Douds (b) (4) (b) (4)	10 Nov 2020 17:00:47

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:55:30

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:32:22
User signature succeeded.	sharon trey (b) (4) (b) (4)	21 Feb 2021 19:36:14
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) (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) (b) (4)	18 Nov 2020 16:20:04
User entered 'AE #1' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (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) (b) (4)	10 Nov 2020 17:00:47