

US3122085 (Prod: M3 Wake Research, Inc - M3 Wake)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:22:03

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US3122085

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 20:55:56

Generated On: 09 Jun 2021 15:22:03

Participant ID

US3122085

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

US3122085

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:56:21

Generated On: 09 Jun 2021 15:22:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 JUL 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

US3122085

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 20:56:21

Generated On: 09 Jun 2021 15:22:03

Date of Birth (MMM yyyy)	(b) (6) 1950
Age	69
Age Units	YEARS
Age (Derived)	69
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 20:56:21

Generated On: 09 Jun 2021 15:22:03

Date of Informed Consent (*dd MMM yyyy*) 28 JUL 2020

Month and Year of Informed Consent (derived) JUL 2020

Year of Informed Consent (derived) 2020

Protocol Version Amendment 1 ☒
Amendment 2 ☐
Amendment 3 ☐
Amendment 4 ☐
Amendment 5 ☐

Was participant enrolled in the study? Yes ☒
No ☐

If No, indicate reason for screen fail Withdrew Consent ☐
Inclusion/Exclusion ☐
Cohort Full ☐
Other ☐

If reason for screen fail is Other, specify _____
Was this participant screened previously? Yes ☐
No ☒

If Yes, previous participant number _____
Enrollment Trigger 1

US3122085

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 20:56:21

Generated On: 09 Jun 2021 15:22:03

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 20:56:21

Generated On: 09 Jun 2021 15:22:03

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 12 Apr 2021 16:59:04

Generated On: 09 Jun 2021 15:22:03

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Apr 2021 16:59:04

Generated On: 09 Jun 2021 15:22:03

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Start Year (derived)	2002
Stop Month and Year (derived)	
Stop Year (derived)	

US3122085

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Apr 2021 16:59:04

Generated On: 09 Jun 2021 15:22:03

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

US3122085

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Apr 2021 16:59:04

Generated On: 09 Jun 2021 15:22:03

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3122085

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Apr 2021 16:59:04

Generated On: 09 Jun 2021 15:22:03

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

US3122085

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 12 Apr 2021 16:59:04

Generated On: 09 Jun 2021 15:22:03

Condition	MELANOMA REMOVAL - BACK
Start date (dd MMM yyyy)	UN UNK 2011
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 2011
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	JAN 2011
Stop Year (derived)	2011

US3122085

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 12 Apr 2021 16:59:04

Generated On: 09 Jun 2021 15:22:03

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 12 Apr 2021 16:59:04

Generated On: 09 Jun 2021 15:22:03

Condition	AXILLARY LYMPH NODE REMOVAL (SECONDARY TO SKIN CANCER REMOVAL)
Start date (dd MMM yyyy)	UN UNK 2011
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 2011
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	JAN 2011
Stop Year (derived)	2011

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 12 Apr 2021 16:59:04

Generated On: 09 Jun 2021 15:22:03

Condition	APPENDECTOMY
Start date (dd MMM yyyy)	UN UNK 1979
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 1979
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1979
Start Year (derived)	1979
Stop Month and Year (derived)	JAN 1979
Stop Year (derived)	1979

US3122085

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 12 Apr 2021 16:59:04

Generated On: 09 Jun 2021 15:22:03

Condition	GASTRIC BANDING SURGERY
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	JAN 2001
Stop Year (derived)	2001

US3122085

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 12 Apr 2021 16:59:04

Generated On: 09 Jun 2021 15:22:03

Condition	MELANOMA - BACK
Start date (dd MMM yyyy)	UN UNK 2011
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 2011
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	JAN 2011
Stop Year (derived)	2011

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 12 Apr 2021 16:59:04

Generated On: 09 Jun 2021 15:22:03

Condition	DIVERTICULITIS
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 20:56:21

Generated On: 09 Jun 2021 15:22:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 JUL 2020
Time of assessment (00:00-23:59)	15:06 (24 HR)
Vital Signs Date and Time (derived)	28 JUL 2020 15:06
Height (xxx.x)	70 in
Weight (xxx.x)	239 lb
BMI (xxx.x)	34.36463 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	ND - Not Done
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) 19 Feb 2021 20:56:21

Generated On: 09 Jun 2021 15:22:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 JUL 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 20:56:21

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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 RETIRED

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 20:56:21

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:56:21

Generated On: 09 Jun 2021 15:22:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 JUL 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) 19 Feb 2021 20:56:21

Generated On: 09 Jun 2021 15:22:03

What was the date of randomization? (dd MMM yyyy) 28 JUL 2020

What was the participant's randomization number? 184101

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 20:56:21

Generated On: 09 Jun 2021 15:22:03

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) 19 Feb 2021 20:56:21

Generated On: 09 Jun 2021 15:22:03

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)	28 JUL 2020
Time of assessment (00:00-23:59)	15:06 (24 HR)
Vital Signs Date and Time (derived)	28 JUL 2020 15:06
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	49 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 20:56:21

Generated On: 09 Jun 2021 15:22:03

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)	28 JUL 2020
Time of assessment (00:00-23:59)	17:12 (24 HR)
Vital Signs Date and Time (derived)	28 JUL 2020 17:12
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	50 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:56:21

Generated On: 09 Jun 2021 15:22:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 JUL 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: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 20:56:21

Generated On: 09 Jun 2021 15:22:03

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) 28 JUL 2020

What was the treatment time? (00:00-23:59) 16:45 (24 HR)

Treatment Date and Time (derived) 28 JUL 2020 16:45

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) 19 Feb 2021 20:56:21

Generated On: 09 Jun 2021 15:22:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 JUL 2020

Collection time (00:00-23:59)

16:22 (24 HR)

Collection date and time (derived)

28 JUL 2020 16:22

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 20:56:21

Generated On: 09 Jun 2021 15:22:03

Collection date (dd MMM yyyy)			28 JUL 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:28	28 JUL 2020 16:28
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:56:21

Generated On: 09 Jun 2021 15:22:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

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

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

Yes ☐
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

28 JUL 2020 17:05

PC Close Date & Time

28 JUL 2020 19:35

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

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 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	28 JUL 2020 22:23
PC Open Date & Time	28 JUL 2020 20:30
PC Close Date & Time	29 JUL 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:22:03

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

97.1 °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

29 JUL 2020 22:07

PC Open Date & Time

29 JUL 2020 12:00

PC Close Date & Time

30 JUL 2020 11:59

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.3 °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

30 JUL 2020 21:46

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:22:03

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

96.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 JUL 2020 22:28

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 AUG 2020 21:51

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 AUG 2020 00:38

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 AUG 2020 23:04

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

28 JUL 2020 17:05

PC Close Date & Time

28 JUL 2020 19:35

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 JUL 2020 22:24

PC Open Date & Time

28 JUL 2020 20:30

PC Close Date & Time

29 JUL 2020 11:59

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:22:03

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

29 JUL 2020 22:09

PC Open Date & Time

29 JUL 2020 12:00

PC Close Date & Time

30 JUL 2020 11:59

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:22:03

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

30 JUL 2020 21:47

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:22:03

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

31 JUL 2020 22:29

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:22:03

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

01 AUG 2020 21:52

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 AUG 2020 00:39

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:22:03

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

03 AUG 2020 23:04

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

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 ☐

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

28 JUL 2020 17:05

PC Close Date & Time

28 JUL 2020 19:35

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

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 ☐

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

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

No ☒

Yes ☐

PC Time stamp	28 JUL 2020 22:25
PC Open Date & Time	28 JUL 2020 20:30
PC Close Date & Time	29 JUL 2020 11:59

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:22:03

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 ☒

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:22:03

Yes <input type="checkbox"/>	
PC Time stamp	29 JUL 2020 22:10
PC Open Date & Time	29 JUL 2020 12:00
PC Close Date & Time	30 JUL 2020 11:59

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:22:03

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

55 of 2406

EAB) (1725)

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:22:03

Yes <input type="checkbox"/>	
PC Time stamp	30 JUL 2020 21:49
PC Open Date & Time	30 JUL 2020 12:00
PC Close Date & Time	31 JUL 2020 11:59

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:22:03

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

57 of 2406

EAB) (1725)

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:22:03

Yes <input type="checkbox"/>	
PC Time stamp	31 JUL 2020 22:29
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

59 of 2406

EAB) (1725)

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:22:03

Yes <input type="checkbox"/>	
PC Time stamp	01 AUG 2020 21:52
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:22:03

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

61 of 2406

EAB) (1725)

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:22:03

Yes <input type="checkbox"/>	
PC Time stamp	03 AUG 2020 00:40
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:22:03

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 ☒

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:22:03

Yes <input type="checkbox"/>	
PC Time stamp	03 AUG 2020 23:05
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3122085

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3122085

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3122085

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3122085

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3122085

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:56:21

Generated On: 09 Jun 2021 15:22:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122085

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:56:21

Generated On: 09 Jun 2021 15:22:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122085

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:55:57

Generated On: 09 Jun 2021 15:22:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122085

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:55:57

Generated On: 09 Jun 2021 15:22:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122085

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:55:57

Generated On: 09 Jun 2021 15:22:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122085

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:55:57

Generated On: 09 Jun 2021 15:22:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122085

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:56:21

Generated On: 09 Jun 2021 15:22:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3122085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 20:56:21

Generated On: 09 Jun 2021 15:22:03

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 AUG 2020
Time of assessment (00:00-23:59)	15:18 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 15:18
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3122085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 20:56:21

Generated On: 09 Jun 2021 15:22:03

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 AUG 2020
Time of assessment (00:00-23:59)	17:12 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 17:12
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3122085

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:56:21

Generated On: 09 Jun 2021 15:22:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 AUG 2020

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

US3122085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 20:56:21

Generated On: 09 Jun 2021 15:22:03

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 16:35 (24 HR)

Treatment Date and Time (derived) 26 AUG 2020 16:35

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

US3122085

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 20:56:21

Generated On: 09 Jun 2021 15:22:03

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 AUG 2020
Collection time (00:00-23:59)	15:55 (24 HR)
Collection date and time (derived)	26 AUG 2020 15:55

US3122085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 20:56:21

Generated On: 09 Jun 2021 15:22:03

Collection date (dd MMM yyyy)			26 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:55	26 AUG 2020 16:55
Nasopharyngeal Swab 2	No		

US3122085

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:56:21

Generated On: 09 Jun 2021 15:22:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐
No ☒

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

PC Time Stamp	26 AUG 2020 17:07
PC Open Date & Time	26 AUG 2020 16:55
PC Close Date & Time	26 AUG 2020 19:25

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

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 96.9 °F

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

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

PC Time Stamp	26 AUG 2020 21:40
PC Open Date & Time	26 AUG 2020 20:20
PC Close Date & Time	27 AUG 2020 11:59

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:22:03

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

97.1 °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

27 AUG 2020 20:41

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:22:03

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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 21:34

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:22:03

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 23:58

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 23:07

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 23:13

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 21:30

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 17:09

PC Open Date & Time

26 AUG 2020 16:55

PC Close Date & Time

26 AUG 2020 19:25

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 21:40

PC Open Date & Time

26 AUG 2020 20:20

PC Close Date & Time

27 AUG 2020 11:59

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 20:42

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 21:35

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 23:59

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 23:08

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 23:14

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 21:31

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

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 ☐

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 17:10
PC Open Date & Time	26 AUG 2020 16:55
PC Close Date & Time	26 AUG 2020 19:25

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

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 ☐

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 21:41
PC Open Date & Time	26 AUG 2020 20:20
PC Close Date & Time	27 AUG 2020 11:59

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☒

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:22:03

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 20:45
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:22:03

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 ☒

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:22:03

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 21:37
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:22:03

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 ☒

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:22:03

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 00:00
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:22:03

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 23:09
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:22:03

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 ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:22:03

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 23:14
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:22:03

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 ☒

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EAB) (1725)

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:22:03

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 21:33
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3122085

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 02 SEP 2020 21:21

PC Open Date & Time 02 SEP 2020 12:00

PC Close Date & Time 03 SEP 2020 11:59

US3122085

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	02 SEP 2020 21:21
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3122085

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:55:57

Generated On: 09 Jun 2021 15:22:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122085

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:55:57

Generated On: 09 Jun 2021 15:22:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122085

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:55:57

Generated On: 09 Jun 2021 15:22:03

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3122085

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:55:57

Generated On: 09 Jun 2021 15:22:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122085

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:56:21

Generated On: 09 Jun 2021 15:22:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122085

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:56:21

Generated On: 09 Jun 2021 15:22:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122085

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:56:21

Generated On: 09 Jun 2021 15:22:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 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	VISIT3

US3122085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 20:56:21

Generated On: 09 Jun 2021 15:22:03

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) _____

US3122085

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:56:21

Generated On: 09 Jun 2021 15:22:03

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.

US3122085

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 20:56:21

Generated On: 09 Jun 2021 15:22:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 SEP 2020

Collection time (00:00-23:59)

15:20 (24 HR)

Collection date and time (derived)

25 SEP 2020 15:20

US3122085

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:56:21

Generated On: 09 Jun 2021 15:22:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 SEP 2020 00:41:07
Patient Cloud Open Date & Time	27 SEP 2020 00:01
Patient Cloud Close Date & Time	01 OCT 2020 23:59

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 OCT 2020 19:15:42

Patient Cloud Open Date & Time

04 OCT 2020 00:01

Patient Cloud Close Date & Time

08 OCT 2020 23:59

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	11 OCT 2020 15:30:17
Patient Cloud Open Date & Time	11 OCT 2020 00:01
Patient Cloud Close Date & Time	15 OCT 2020 23:59

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 OCT 2020 13:57:13

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT	DAY 99
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	02 NOV 2020 16:39:14
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

10 NOV 2020 10:03:01

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT	DAY 113
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 checked="" 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"/>
Have 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 checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	True
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	False
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" 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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	17 NOV 2020 17:47:58
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" 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"/>
Have 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	26 NOV 2020 00:56:02
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 DEC 2020 00:23:59

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 DEC 2020 11:38:03

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 DEC 2020 12:46:00

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

24 DEC 2020 00:56:41

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 DEC 2020 11:13:22

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 JAN 2021 14:55:29
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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 <input type="radio"/> Yes <input checked="" 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"/>
Have 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
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 checked="" 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 checked="" type="radio"/>
Date and time of submission	14 JAN 2021 15:55:00
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 JAN 2021 11:04:14

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 JAN 2021 10:37:54

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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	04 FEB 2021 10:56:28
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" 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"/>
Have 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 checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	False
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" 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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	11 FEB 2021 12:52:22
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

18 FEB 2021 11:38:54

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 FEB 2021 10:24:37

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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 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	04 MAR 2021 00:25:27
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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 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	11 MAR 2021 18:39:45
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 MAR 2021 15:50:26
Patient Cloud Open Date & Time	18 MAR 2021 00:01
Patient Cloud Close Date & Time	22 MAR 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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 checked="" 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"/>
Have 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	26 MAR 2021 19:28:02
Patient Cloud Open Date & Time	25 MAR 2021 00:01
Patient Cloud Close Date & Time	29 MAR 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 APR 2021 13:11:01

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 APR 2021 12:52:46

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 01:38:15

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 01:25:01

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 278

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 12:52:31

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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="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"/>

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 306

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 313

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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"/>

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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"/>

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 JUL 2021 00:01
Patient Cloud Close Date & Time	12 JUL 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2021 00:01
Patient Cloud Close Date & Time	19 JUL 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 369

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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"/>

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

Patient Cloud Open Date & Time	26 AUG 2021 00:01
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Patient Cloud Close Date & Time	30 AUG 2021 23:59
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US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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"/>

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 SEP 2021 00:01
Patient Cloud Close Date & Time	13 SEP 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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"/>

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 425

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 432

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 439

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 OCT 2021 00:01
Patient Cloud Close Date & Time	11 OCT 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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"/>

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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="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"/>

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

Patient Cloud Open Date & Time	21 OCT 2021 00:01
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Patient Cloud Close Date & Time	25 OCT 2021 23:59
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US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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="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"/>

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

Patient Cloud Open Date & Time	11 NOV 2021 00:01
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Patient Cloud Close Date & Time	15 NOV 2021 23:59
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US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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"/>

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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"/>

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 DEC 2021 00:01
Patient Cloud Close Date & Time	06 DEC 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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 ☐

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

16 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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 <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"/>

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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 ☐

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 JAN 2022 00:01
Patient Cloud Close Date & Time	17 JAN 2022 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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 <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"/>

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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°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 ☐

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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 ☐

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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 ☐

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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"/>

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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"/>

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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"/>

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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"/>

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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"/>

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 MAY 2022 00:01
Patient Cloud Close Date & Time	16 MAY 2022 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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"/>

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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"/>

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 JUN 2022 00:01
Patient Cloud Close Date & Time	04 JUL 2022 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 JUL 2022 00:01
Patient Cloud Close Date & Time	18 JUL 2022 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 726

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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"/>

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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"/>

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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"/>

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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"/>

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 AUG 2022 00:01
Patient Cloud Close Date & Time	29 AUG 2022 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 775

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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 ☐

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2022 00:01
Patient Cloud Close Date & Time	26 SEP 2022 23:59

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

DAY 796

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3122085

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:22:03

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		28 FEB 2021 11:01:26

US3122085

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:56:21

Generated On: 09 Jun 2021 15:22:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122085

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:56:21

Generated On: 09 Jun 2021 15:22:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122085

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:55:56

Generated On: 09 Jun 2021 15:22:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122085

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:55:56

Generated On: 09 Jun 2021 15:22:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122085

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:55:57

Generated On: 09 Jun 2021 15:22:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122085

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:55:56

Generated On: 09 Jun 2021 15:22:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122085

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:55:57

Generated On: 09 Jun 2021 15:22:03

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

US3122085

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:55:57

Generated On: 09 Jun 2021 15:22:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122085

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 17:22:46

Generated On: 09 Jun 2021 15:22:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 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	VISIT4

US3122085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 30 Mar 2021 13:55:01

Generated On: 09 Jun 2021 15:22:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	15 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	10:11 (24 HR)
Vital Signs Date and Time (derived)	15 FEB 2021 10:11
Temperature (<i>xxx.x</i>)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	61 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	87 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3122085

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 17:22:46

Generated On: 09 Jun 2021 15:22:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 FEB 2021

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

US3122085

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 21:02:57

Generated On: 09 Jun 2021 15:22:03

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 FEB 2021
Collection time (00:00-23:59)	10:30 (24 HR)
Collection date and time (derived)	15 FEB 2021 10:30

US3122085

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 17:22:46

Generated On: 09 Jun 2021 15:22:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122085

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 24 Mar 2021 18:31:07

Generated On: 09 Jun 2021 15:22:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122085

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 24 Mar 2021 18:31:07

Generated On: 09 Jun 2021 15:22:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122085

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 14:11:17

Generated On: 09 Jun 2021 15:22:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122085

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 14:11:17

Generated On: 09 Jun 2021 15:22:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122085

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

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

US3122085

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 19 Feb 2021 20:55:56

Generated On: 09 Jun 2021 15:22:03

Date of Contact	18 NOV 2020
Time of Contact	14:06
Date and Time of Contact (derived)	18 NOV 2020 14:06
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 20:55:56

Generated On: 09 Jun 2021 15:22:03

Symptom Day

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

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 20:55:56

Generated On: 09 Jun 2021 15:22:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

330 of 2406

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 20:55:56

Generated On: 09 Jun 2021 15:22:03

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

331 of 2406

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 20:55:56

Generated On: 09 Jun 2021 15:22:03

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

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 19 Feb 2021 20:55:56

Generated On: 09 Jun 2021 15:22:03

Date of Visit	18 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	18 NOV 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 19 Mar 2021 17:08:37

Generated On: 09 Jun 2021 15:22:03

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3122085

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 19 Mar 2021 17:08:37

Generated On: 09 Jun 2021 15:22:03

Visit	Was Saliva Collected?	Date of Collection
Day 3	No	
Day 5	No	
Day 7	No	
Day 9	No	
Day 14	No	
Day 21	No	
Day 28	No	

US3122085

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:55:56

Generated On: 09 Jun 2021 15:22:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 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	SICKD1

US3122085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 20:55:56

Generated On: 09 Jun 2021 15:22:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 NOV 2020
Time of assessment (00:00-23:59)	14:11 (24 HR)
Vital Signs Date and Time (derived)	18 NOV 2020 14:11
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	97.1 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)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3122085

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:55:56

Generated On: 09 Jun 2021 15:22:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 NOV 2020

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

US3122085

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 19 Feb 2021 20:55:56

Generated On: 09 Jun 2021 15:22:03

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

18 NOV 2020

US3122085

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

Form: Visit Date

Data signed: (b) (4) 22 Mar 2021 15:04:49

Generated On: 09 Jun 2021 15:22:03

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

Visit date (dd MMM yyyy)	14 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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US3122085

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

Form: Unblinding

Data signed: (b) (4) 22 Mar 2021 15:04:49

Generated On: 09 Jun 2021 15:22:03

Date of updated informed consent (<i>dd MMM yyyy</i>)	14 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>)	14 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3122085

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 20:55:56

Generated On: 09 Jun 2021 15:22:03

Height	
Weight	
BMI (xxx.x)	

US3122085

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 20:55:56

Generated On: 09 Jun 2021 15:22:03

Height	
Weight	
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)	14 JAN 2021
Time of assessment (00:00-23:59)	10:20 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 10:20
Temperature (xxx.x)	98.1 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)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3122085

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 20:55:56

Generated On: 09 Jun 2021 15:22:03

Height	
Weight	
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)	14 JAN 2021
Time of assessment (00:00-23:59)	11:34 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 11:34
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3122085

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

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:55:56

Generated On: 09 Jun 2021 15:22:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 JAN 2021

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

US3122085

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

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 20:55:56

Generated On: 09 Jun 2021 15:22:03

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) 14 JAN 2021

What was the treatment time? (00:00-23:59) 11:00 (24 HR)

Treatment Date and Time (derived) 14 JAN 2021 11:00

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

US3122085

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 20:55:56

Generated On: 09 Jun 2021 15:22:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 JAN 2021

Collection time (00:00-23:59)

10:49 (24 HR)

Collection date and time (derived)

14 JAN 2021 10:49

US3122085

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 20:55:56

Generated On: 09 Jun 2021 15:22:03

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00 - 23:59)	10:50
Collection Date and Time (derived)	14 JAN 2021 10:50

US3122085

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

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:55:56

Generated On: 09 Jun 2021 15:22:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122085

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:56:21

Generated On: 09 Jun 2021 15:22:03

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

US3122085

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:56:21

Generated On: 09 Jun 2021 15:22:03

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

US3122085

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 17:22:46

Generated On: 09 Jun 2021 15:22:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 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

US3122085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Mar 2021 17:22:46

Generated On: 09 Jun 2021 15:22:03

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)	15 FEB 2021
Time of assessment (00:00-23:59)	10:11 (24 HR)
Vital Signs Date and Time (derived)	15 FEB 2021 10:11
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3122085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Mar 2021 17:22:46

Generated On: 09 Jun 2021 15:22:03

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)	15 FEB 2021
Time of assessment (00:00-23:59)	11:44 (24 HR)
Vital Signs Date and Time (derived)	15 FEB 2021 11:44
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	53 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3122085

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 17:22:46

Generated On: 09 Jun 2021 15:22:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 FEB 2021

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

US3122085

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 12 Mar 2021 17:22:46

Generated On: 09 Jun 2021 15:22:03

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) 15 FEB 2021

What was the treatment time? (00:00-23:59) 10:48 (24 HR)

Treatment Date and Time (derived) 15 FEB 2021 10:48

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

US3122085

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 17:22:46

Generated On: 09 Jun 2021 15:22:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122085

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 17:08:37

Generated On: 09 Jun 2021 15:22:03

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

US3122085

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 17:08:37

Generated On: 09 Jun 2021 15:22:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122085

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 17:08:37

Generated On: 09 Jun 2021 15:22:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3122085

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Mar 2021 17:08:37

Generated On: 09 Jun 2021 15:22:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	17 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	11:10 (24 HR)
Vital Signs Date and Time (derived)	17 MAR 2021 11:10
Temperature (<i>xxx.x</i>)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	59 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3122085

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 17:08:37

Generated On: 09 Jun 2021 15:22:03

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.

US3122085

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 17:08:37

Generated On: 09 Jun 2021 15:22:03

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	17 MAR 2021
Collection time (00:00-23:59)	11:12 (24 HR)
Collection date and time (derived)	17 MAR 2021 11:12

US3122085

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 22 Feb 2021 15:07:27

Generated On: 09 Jun 2021 15:22:03

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3122085

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Mar 2021 19:17:52

Generated On: 09 Jun 2021 15:22:03

AEID	USA-US063-2021-MRNA-1273-P30 1000001
Adverse event	DIVERTICULITIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	08 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	13 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	08 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	13 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Mar 2021 19:17:52

Generated On: 09 Jun 2021 15:22:03

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 checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input 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	

US3122085

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Mar 2021 19:17:52

Generated On: 09 Jun 2021 15:22:03

SUBJECT WOKE UP AT 3:30 AM
OF 08JAN2021 HAVING BRIGHT
RED BLOODY STOOLS ON
SEVERAL OCCASIONS.
SUBJECT STATED HE FELT
LIGHT HEADED AND SWEATY
AROUND 7:00 AM AND
DECIDED TO GO TO THE
URGENT CARE WHO DIRECTED
SUBJECT TO GO TO THE DUKE
EMERGENCY ROOM. SUBJECT
WAS ADMITTED OVERNIGHT
WHERE BLOODWORK AND CAT
SCAN WAS PERFORMED IN ER
SUBJECT STATES HIS HGB WAS
12 AND LATER DROPPED TO 10
OVERNIGHT. SUBJECT STATES
THAT HGB WENT BACK TO 11.8
BY DISCHARGE. ON 09JAN2021,
SHOWED SUBJECT TO HAVE
DIVERTICULITIS WHICH WAS
NOTED ON A PREVIOUS
COLONOSCOPY AT LEAST 15
YEARS AGO. PER THE
HOSPITAL GI DOCTORS, THEY
TOLD THE SUBJECT BLEEDING
WOULD STOP ON ITS OWN.
SUBJECT WAS DISCHARGED
WITH NO MEDICATION AND
RECEIVED NONE IN ER WHILE
ADMITTED.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 20:55:56

Generated On: 09 Jun 2021 15:22:03

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

Yes ☒

No ☐

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

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 14 Apr 2021 19:41:46

Generated On: 09 Jun 2021 15:22:03

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GERD

Dose per administration 40

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 (1)

Data signed: (b) (4) 14 Apr 2021 19:41:46

Generated On: 09 Jun 2021 15:22:03

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

Data signed: (b) (4) 14 Apr 2021 19:41:46

Generated On: 09 Jun 2021 15:22:03

Name of Medication SERTRALINE

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 25

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 (2)

Data signed: (b) (4) 14 Apr 2021 19:41:46

Generated On: 09 Jun 2021 15:22:03

	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 1995	
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) 14 Apr 2021 19:41:46

Generated On: 09 Jun 2021 15:22:03

Name of Medication WELLBUTRIN

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 300

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 (3)

Data signed: (b) (4) 14 Apr 2021 19:41:46

Generated On: 09 Jun 2021 15:22:03

	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 2005	
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) 14 Apr 2021 19:41:46

Generated On: 09 Jun 2021 15:22:03

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 100

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 (4)

Data signed: (b) (4) 14 Apr 2021 19:41:46

Generated On: 09 Jun 2021 15:22:03

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

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 14 Apr 2021 19:41:46

Generated On: 09 Jun 2021 15:22:03

Name of Medication SIMVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 80

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 (5)

Data signed: (b) (4) 14 Apr 2021 19:41:46

Generated On: 09 Jun 2021 15:22:03

	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 2005	
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"/>

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 14 Apr 2021 19:41:46

Generated On: 09 Jun 2021 15:22:03

Name of Medication ZETIA

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 10

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 (6)

Data signed: (b) (4) 14 Apr 2021 19:41:46

Generated On: 09 Jun 2021 15:22:03

	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 2005	
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 (7)

Data signed: (b) (4) 14 Apr 2021 19:41:46

Generated On: 09 Jun 2021 15:22:03

Name of Medication SODIUM SULFATEMIDE

Prophylaxis Yes ☐
No ☒

Indication ROSACEA - FACE

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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 (7)

Data signed: (b) (4) 14 Apr 2021 19:41:46

Generated On: 09 Jun 2021 15:22:03

	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 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 14 Apr 2021 19:41:46

Generated On: 09 Jun 2021 15:22:03

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC HEALTH

Dose per administration 325

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 (8)

Data signed: (b) (4) 14 Apr 2021 19:41:46

Generated On: 09 Jun 2021 15:22:03

	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 2019	
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 (9)

Data signed: (b) (4) 14 Apr 2021 19:41:46

Generated On: 09 Jun 2021 15:22:03

Name of Medication CLARITIN

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

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 (9)

Data signed: (b) (4) 14 Apr 2021 19:41:46

Generated On: 09 Jun 2021 15:22:03

	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 JUN 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) _____		
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 (10)

Data signed: (b) (4) 14 Apr 2021 19:41:46

Generated On: 09 Jun 2021 15:22:03

Name of Medication NIACINAMIDE

Prophylaxis Yes ☐
No ☒

Indication ROSACEA - FACE

Dose per administration 500

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 (10)

Data signed: (b) (4) 14 Apr 2021 19:41:46

Generated On: 09 Jun 2021 15:22:03

	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 2019	
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 (11)

Data signed: (b) (4) 14 Apr 2021 19:41:46

Generated On: 09 Jun 2021 15:22:03

Name of Medication MONTELEUKAST NA

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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 (11)

Data signed: (b) (4) 14 Apr 2021 19:41:46

Generated On: 09 Jun 2021 15:22:03

	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)	10 MAR 2021	
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 (12)

Data signed: (b) (4) 14 Apr 2021 19:41:46

Generated On: 09 Jun 2021 15:22:03

Name of Medication SHINGREX DOSE 1

Prophylaxis Yes ☒
No ☐

Indication SHINGLES PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 14 Apr 2021 19:41:46

Generated On: 09 Jun 2021 15:22:03

	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)		17 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		17 NOV 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 (13)

Data signed: (b) (4) 14 Apr 2021 19:41:46

Generated On: 09 Jun 2021 15:22:03

Name of Medication SHINGREX DOSE 2

Prophylaxis Yes ☒
No ☐

Indication SHINGLES PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 14 Apr 2021 19:41:46

Generated On: 09 Jun 2021 15:22:03

	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)	23 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		23 MAR 2021
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 (14)

Data signed: (b) (4) 14 Apr 2021 19:41:46

Generated On: 09 Jun 2021 15:22:03

Name of Medication	FLU SHOT
Prophylaxis	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Indication	FLU PREVENTION
Dose per administration	1
Dose unit	mg <input type="radio"/>
	ug <input type="radio"/>
	mL <input type="radio"/>
	g <input type="radio"/>
	IU <input type="radio"/>
	tablet <input type="radio"/>
	capsule <input type="radio"/>
	puff <input type="radio"/>
	Other <input checked="" type="radio"/>

If dose unit is Other, specify	INJECTION
Frequency	once daily <input type="radio"/>
	twice daily <input type="radio"/>
	three times daily <input type="radio"/>
	four times daily <input type="radio"/>
	every other day <input type="radio"/>
	every week <input type="radio"/>
	every month <input type="radio"/>
	as needed <input type="radio"/>
	once <input checked="" type="radio"/>
	unknown <input type="radio"/>
	other <input type="radio"/>

If frequency is Other, specify	
Route of administration	Oral <input type="radio"/>
	Topical <input type="radio"/>
	Subcutaneous <input type="radio"/>
	Transdermal <input type="radio"/>
	Intraocular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 14 Apr 2021 19:41:46

Generated On: 09 Jun 2021 15:22:03

	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)		17 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		17 NOV 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"/>

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 14 Apr 2021 19:41:46

Generated On: 09 Jun 2021 15:22:03

Name of Medication TETANUS SHOT

Prophylaxis Yes ☒
No ☐

Indication TETANUS PREVENTION

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 (15)

Data signed: (b) (4) 14 Apr 2021 19:41:46

Generated On: 09 Jun 2021 15:22:03

	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)		11 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		11 DEC 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 Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 22 Mar 2021 15:04:49

Generated On: 09 Jun 2021 15:22:03

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 22 Mar 2021 15:04:49

Generated On: 09 Jun 2021 15:22:03

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
08 JAN 2021	CAT SCAN	Adverse Event	
08 JAN 2021	BLOODWORK	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:22:03

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:22:03

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 ☐

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 23 Mar 2021 19:17:52

Generated On: 09 Jun 2021 15:22:03

SAEID	USA-US063-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	WAYNE
Investigator's Last Name	HARPER
Site Address: Street	3100 DURALEIGH RD
Site Address: City	RALEIGH
Site Address: State	NC
Site Address: Postal Code	27612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Mar 2021 19:17:52

Generated On: 09 Jun 2021 15:22:03

SAEID	USA-US063-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	WAYNE
Investigator's Last Name	HARPER
Site Address: Street	3100 DURALEIGH RD
Site Address: City	RALEIGH
Site Address: State	NC
Site Address: Postal Code	27612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	23/FEB/2021 09:21
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Mar 2021 19:17:52

Generated On: 09 Jun 2021 15:22:03

SAEID	USA-US063-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	WAYNE
Investigator's Last Name	HARPER
Site Address: Street	3100 DURALEIGH RD
Site Address: City	RALEIGH
Site Address: State	NC
Site Address: Postal Code	27612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	23/MAR/2021 12:26
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3122085 (Prod: M3 Wake Research, Inc - M3 Wake)

US3122085

Form: Participant Creation

Generated On: 09 Jun 2021 15:22:03

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'US3122085'	(b) (4) RWS_ENDPOINT ENDPOINT(b) (4)	28 Jul 2020 19:39:24

US3122085

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:22:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	28 Jul 2020 23:54:52

US3122085

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:22:03

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '28 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT(b) (4)	28 Jul 2020 19:39:24

US3122085

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Clinic (Clinic)'	(b) (4) Leah Corts (b) (4)	28 Jul 2020 23:54:52

US3122085

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:22:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered 'SCRN'	System	28 Jul 2020 23:54:52

US3122085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:22:03

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered (b) (6) 1950'	(b) (4) RWS_ENDPOINT ENDPOINT(b) (4)	28 Jul 2020 19:39:25

US3122085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:22:03

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '69'	(b) (4) Leah Corts (b) (4)	28 Jul 2020 23:54:45

US3122085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:22:03

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered 'YEARS'	System	28 Jul 2020 23:54:45

US3122085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:22:03

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered '69'	System	28 Jul 2020 23:55:20

US3122085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:22:03

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Male (M)'	(b) (4) Leah Corts (b) (4)	28 Jul 2020 23:54:45

US3122085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:22:03

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Leah Corts (b) (4)	28 Jul 2020 23:54:45

US3122085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:22:03

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'I'	(b) (4) Leah Corts (b) (4)	28 Jul 2020 23:54:45

US3122085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:22:03

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '0'	(b) (4) Leah Corts (b) (4)	28 Jul 2020 23:54:45

US3122085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:22:03

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '0'	(b) (4) Leah Corts (b) (4)	28 Jul 2020 23:54:45

US3122085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:22:03

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '0'	(b) (4) Leah Corts (b) (4)	28 Jul 2020 23:54:45

US3122085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:22:03

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '0'	(b) (4) Leah Corts (b) (4)	28 Jul 2020 23:54:45

US3122085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:22:03

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '0'	(b) (4) Leah Corts (b) (4)	28 Jul 2020 23:54:45

US3122085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:22:03

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered empty.	(b) (4) Leah Corts (b) (4)	28 Jul 2020 23:54:45

US3122085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:22:03

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '0'	(b) (4) Leah Corts (b) (4)	28 Jul 2020 23:54:45

US3122085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:22:03

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '0'	(b) (4) Leah Corts (b) (4)	28 Jul 2020 23:54:45

US3122085

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:22:03

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '28 Jul 2020'	(b) (4) Leah Corts (b) (4)	28 Jul 2020 23:55:20

US3122085

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered 'Jul 2020'	System	28 Jul 2020 23:55:20

US3122085

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered '2020'	System	28 Jul 2020 23:55:20

US3122085

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:22:03

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Amendment 1 (1)'	(b) (4) Leah Corts (b) (4)	28 Jul 2020 23:55:20

US3122085

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	28 Jul 2020 23:55:20

US3122085

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:22:03

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered empty.	(b) (4) Leah Corts (b) (4)	28 Jul 2020 23:55:20

US3122085

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:22:03

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered empty.	(b) (4) Leah Corts (b) (4)	28 Jul 2020 23:55:20

US3122085

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:22:03

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	28 Jul 2020 23:55:20

US3122085

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:22:03

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT(b) (4)	28 Jul 2020 19:39:24

US3122085

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:22:03

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered 'I'	System	28 Jul 2020 23:55:27

US3122085

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	28 Jul 2020 23:55:27

US3122085

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:22:03

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 19:57:01

US3122085

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:22:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 19:59:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 19:59:13
Data point term sent to Coder	System	31 Jul 2020 19:58:10
User entered 'Hypertension'	Brad Killebrew (b) (4)	31 Jul 2020 19:57:29

US3122085

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'un UNK 2000'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 19:57:29

US3122085

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:22:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 19:57:29

US3122085

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:22:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 19:57:29

US3122085

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 19:57:29

US3122085

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:22:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 19:57:29

US3122085

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:22:03

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered 'Jan 2000'	System	31 Jul 2020 19:57:29

US3122085

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered '2000'	System	31 Jul 2020 19:57:29

US3122085

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered empty.	System	31 Jul 2020 19:57:29

US3122085

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered empty.	System	31 Jul 2020 19:57:29

US3122085

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:22:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 20:00:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 20:00:14
Data point term sent to Coder	System	31 Jul 2020 19:59:10
User entered 'Hyperlipidemia'	Brad Killebrew (b) (4)	31 Jul 2020 19:58:16

US3122085

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'un UNK 2002'	Brad Killebrew (b) (4)	31 Jul 2020 19:58:16

US3122085

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:22:03

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '0'	Brad Killebrew (b) (4)	31 Jul 2020 19:58:16

US3122085

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:22:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 19:58:16

US3122085

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered empty.	Brad Killebrew (b) (4)	31 Jul 2020 19:58:16

US3122085

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:22:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 19:58:16

US3122085

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered 'Jan 2002'	System	31 Jul 2020 19:58:16

US3122085

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered '2002'	System	31 Jul 2020 19:58:16

US3122085

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered empty.	System	31 Jul 2020 19:58:16

US3122085

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered empty.	System	31 Jul 2020 19:58:16

US3122085

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:22:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 20:00:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 20:00:14
Data point term sent to Coder	System	31 Jul 2020 19:59:10
User entered 'GERD'	Brad Killebrew (b) (4)	31 Jul 2020 19:58:35

US3122085

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'un UNK 2000'	Brad Killebrew (b) (4)	31 Jul 2020 19:58:35

US3122085

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:22:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 19:58:35

US3122085

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:22:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 19:58:35

US3122085

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 19:58:35

US3122085

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:22:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 19:58:35

US3122085

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered 'Jan 2000'	System	31 Jul 2020 19:58:35

US3122085

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered '2000'	System	31 Jul 2020 19:58:35

US3122085

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered empty.	System	31 Jul 2020 19:58:35

US3122085

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered empty.	System	31 Jul 2020 19:58:35

US3122085

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:22:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 20:00:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 20:00:14
Data point term sent to Coder	System	31 Jul 2020 19:59:10
User entered 'Depression'	Brad Killebrew (b) (4)	31 Jul 2020 19:59:03

US3122085

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'un UNK 1995'	Brad Killebrew (b) (4)	31 Jul 2020 19:59:03

US3122085

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:22:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 19:59:03

US3122085

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:22:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 19:59:03

US3122085

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 19:59:03

US3122085

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:22:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 19:59:03

US3122085

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered 'Jan 1995'	System	31 Jul 2020 19:59:03

US3122085

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered '1995'	System	31 Jul 2020 19:59:03

US3122085

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered empty.	System	31 Jul 2020 19:59:03

US3122085

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered empty.	System	31 Jul 2020 19:59:03

US3122085

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:22:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Rosaceas, PT: Rosacea, LLT: Rosacea - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 20:01:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 20:01:15
Data point term sent to Coder	System	31 Jul 2020 20:00:11
User entered 'Rosacea'	Brad Killebrew (b) (4)	31 Jul 2020 19:59:19

US3122085

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'un UNK 2018'	Brad Killebrew (b) (4)	31 Jul 2020 19:59:19

US3122085

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:22:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '0'	Brad Killebrew (b) (4)	31 Jul 2020 19:59:19

US3122085

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:22:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 19:59:19

US3122085

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 19:59:19

US3122085

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:22:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '0'	Brad Killebrew (b) (4)	31 Jul 2020 19:59:19

US3122085

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:22:03

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered 'Jan 2018'	System	31 Jul 2020 19:59:19

US3122085

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered '2018'	System	31 Jul 2020 19:59:19

US3122085

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered empty.	System	31 Jul 2020 19:59:19

US3122085

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered empty.	System	31 Jul 2020 19:59:19

US3122085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:22:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin lesion excisions, PT: Skin neoplasm excision, LLT: Malignant melanoma excision - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 10:57:17
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 10:57:17
User closed query 'Per DM CLR: Please specify the location and type of SKIN CANCER. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 14:07:07
Data point term sent to Coder	System	28 Sep 2020 15:35:59
Query 'Per DM CLR: Please specify the location and type of SKIN CANCER. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'clarified' (Site from DM).	Leah Corts (b) (4)	28 Sep 2020 15:35:27
Coding entries removed.	Leah Corts (b) (4)	28 Sep 2020 15:35:19
User entered 'Melanoma REMOVAL - Back' reason for change: Data Entry Error	Leah Corts (b) (4)	28 Sep 2020 15:35:19
User opened query 'Per DM CLR: Please specify the location and type of SKIN CANCER. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 12:13:54
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin lesion excisions, PT: Skin neoplasm excision, LLT: Skin cancer excision - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 17:36:07

US3122085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:22:03

[Condition](#)

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) (b) (4) System	03 Aug 2020 17:36:07 31 Jul 2020 20:38:24
User entered 'Skin cancer removal'	Brad Killebrew (b) (4) (b) (4)	31 Jul 2020 20:37:45

US3122085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'un UNK 2011'	Brad Killebrew (b) (4)	31 Jul 2020 20:37:45

US3122085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:22:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:37:45

US3122085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:22:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'No (N)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:37:45

US3122085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'un UNK 2011'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:37:45

US3122085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:22:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:37:45

US3122085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:22:03

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered 'Jan 2011'	System	31 Jul 2020 20:37:45

US3122085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:22:03

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered '2011'	System	31 Jul 2020 20:37:45

US3122085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered 'Jan 2011'	System	31 Jul 2020 20:37:45

US3122085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered '2011'	System	31 Jul 2020 20:37:45

US3122085

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:22:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 20:39:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 20:39:06
Data point term sent to Coder	System	31 Jul 2020 20:38:26
User entered 'Seasonal Allergies'	Brad Killebrew (b) (4)	31 Jul 2020 20:38:06

US3122085

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'un UNK 2000'	Brad Killebrew (b) (4)	31 Jul 2020 20:38:06

US3122085

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:22:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:38:06

US3122085

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:22:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:38:06

US3122085

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered empty.	Brad Killebrew (b) (4)	31 Jul 2020 20:38:06

US3122085

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:22:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '0'	Brad Killebrew (b) (4)	31 Jul 2020 20:38:06

US3122085

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered 'Jan 2000'	System	31 Jul 2020 20:38:06

US3122085

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered '2000'	System	31 Jul 2020 20:38:06

US3122085

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered empty.	System	31 Jul 2020 20:38:06

US3122085

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered empty.	System	31 Jul 2020 20:38:06

US3122085

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:22:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User coded data point as SOC: Surgical and medical procedures, HLGT: Breast therapeutic procedures, HLT: Breast therapeutic procedures NEC, PT: Axillary lymphadenectomy, LLT: Axillary lymphadenectomy - version MedDRA\\23.0.	Coder Import (b) (4)	02 Aug 2020 13:43:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	02 Aug 2020 13:43:14
Data point term sent to Coder	System	31 Jul 2020 20:40:26
User entered 'Axillary Lymph Node removal (secondary to skin cancer removal)'	Brad Killebrew (b) (4)	31 Jul 2020 20:39:36

US3122085

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'un UNK 2011'	Brad Killebrew (b) (4)	31 Jul 2020 20:39:36

US3122085

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:22:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:39:36

US3122085

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:22:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'No (N)'	Brad Killebrew (b) (4)	31 Jul 2020 20:39:36

US3122085

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'un UNK 2011'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:39:36

US3122085

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:22:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:39:36

US3122085

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered 'Jan 2011'	System	31 Jul 2020 20:39:36

US3122085

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered '2011'	System	31 Jul 2020 20:39:36

US3122085

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered 'Jan 2011'	System	31 Jul 2020 20:39:36

US3122085

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered '2011'	System	31 Jul 2020 20:39:36

US3122085

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:22:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendectomy, LLT: Appendectomy - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 20:41:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 20:41:08
Data point term sent to Coder	System	31 Jul 2020 20:40:27
User entered 'Appendectomy'	Brad Killebrew (b) (4)	31 Jul 2020 20:39:57

US3122085

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'un UNK 1979'	Brad Killebrew (b) (4)	31 Jul 2020 20:39:57

US3122085

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:22:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:39:57

US3122085

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:22:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'No (N)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:39:57

US3122085

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'un UNK 1979'	Brad Killebrew (b) (4)	31 Jul 2020 20:39:57

US3122085

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:22:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '0'	Brad Killebrew (b) (4)	31 Jul 2020 20:39:57

US3122085

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:22:03

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered 'Jan 1979'	System	31 Jul 2020 20:39:57

US3122085

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered '1979'	System	31 Jul 2020 20:39:57

US3122085

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered 'Jan 1979'	System	31 Jul 2020 20:39:57

US3122085

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered '1979'	System	31 Jul 2020 20:39:57

US3122085

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:22:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Gastric therapeutic procedures, PT: Gastric banding, LLT: Gastric banding - version MedDRA\23.0.	Coder Import (b) (4)	31 Jul 2020 21:12:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	31 Jul 2020 21:12:12
Data point term sent to Coder	System	31 Jul 2020 20:41:27
User entered 'Gastric Banding Surgery'	Brad Killebrew (b) (4)	31 Jul 2020 20:40:36

US3122085

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'un UNK 2001'	Brad Killebrew (b) (4)	31 Jul 2020 20:40:36

US3122085

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:22:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:40:36

US3122085

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:22:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'No (N)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:40:36

US3122085

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'un UNK 2001'	Brad Killebrew (b) (4)	31 Jul 2020 20:40:36

US3122085

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:22:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '0'	Brad Killebrew (b) (4)	31 Jul 2020 20:40:36

US3122085

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered 'Jan 2001'	System	31 Jul 2020 20:40:36

US3122085

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered '2001'	System	31 Jul 2020 20:40:36

US3122085

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered 'Jan 2001'	System	31 Jul 2020 20:40:36

US3122085

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered '2001'	System	31 Jul 2020 20:40:36

US3122085

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:22:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin melanomas (excl ocular), PT: Malignant melanoma, LLT: Melanoma - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 11:33:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 11:33:58
Data point term sent to Coder	System	28 Sep 2020 15:37:00
User entered 'Melanoma - Back'	Leah Corts (b) (4)	28 Sep 2020 15:36:28

US3122085

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'UN UNK 2011'	(b) (4) Leah Corts (b) (4)	28 Sep 2020 15:36:28

US3122085

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:22:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '0'	(b) (4) Leah Corts (b) (4)	28 Sep 2020 15:36:28

US3122085

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:22:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	28 Sep 2020 15:36:28

US3122085

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'UN UNK 2011'	(b) (4) Leah Corts (b) (4)	28 Sep 2020 15:36:28

US3122085

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:22:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '0'	(b) (4) Leah Corts (b) (4)	28 Sep 2020 15:36:28

US3122085

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:22:03

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered 'Jan 2011'	System	28 Sep 2020 15:36:28

US3122085

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:22:03

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered '2011'	System	28 Sep 2020 15:36:28

US3122085

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered 'Jan 2011'	System	28 Sep 2020 15:36:28

US3122085

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered '2011'	System	28 Sep 2020 15:36:28

US3122085

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:22:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 16:59:05
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Diverticulitis, LLT: Diverticulitis - version MedDRA\\23.0.	Coder Import (b) (4)	12 Apr 2021 14:43:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Apr 2021 14:43:04
Data point term sent to Coder	System	12 Apr 2021 14:41:57
User entered 'Diverticulitis'	(b) (4), (b) (6)	12 Apr 2021 14:41:53

US3122085

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 16:59:05
User entered 'un UNK 2006'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:41:53

US3122085

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:22:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 16:59:05
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:41:53

US3122085

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:22:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 16:59:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:41:53

US3122085

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 16:59:05
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:41:53

US3122085

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:22:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 16:59:05
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:41:53

US3122085

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:22:03

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered 'Jan 2006'	System	12 Apr 2021 14:41:53

US3122085

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:22:03

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered '2006'	System	12 Apr 2021 14:41:53

US3122085

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered empty.	System	12 Apr 2021 14:41:53

US3122085

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered empty.	System	12 Apr 2021 14:41:53

US3122085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	28 Jul 2020 23:56:44

US3122085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '28 Jul 2020'	(b) (4) Leah Corts (b) (4)	28 Jul 2020 23:56:44

US3122085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '15:06'	(b) (4) Leah Corts (b) (4)	28 Jul 2020 23:56:44

US3122085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered '28 Jul 2020 15:06'	System	28 Jul 2020 23:56:44

US3122085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '70' in	(b) (4) Leah Corts (b) (4)	28 Jul 2020 23:56:44
DataPoint set to visible.	System	28 Jul 2020 23:55:27

US3122085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '239' lb	(b) (4) Leah Corts (b) (4)	28 Jul 2020 23:56:44
DataPoint set to visible.	System	28 Jul 2020 23:55:27

US3122085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
Amendment Manager: User entered '34.36463'	System	16 Sep 2020 23:37:36
User entered '34.4'	System	28 Jul 2020 23:56:44
DataPoint set to visible.	System	28 Jul 2020 23:55:27

US3122085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered 'kg/m2'	System	28 Jul 2020 23:56:44
DataPoint set to visible.	System	28 Jul 2020 23:55:27

US3122085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	18 Aug 2020 13:44:25
User entered '98.2' F	Leah Corts (b) (4)	28 Jul 2020 23:56:44

US3122085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User closed query 'Per CDM: Since Temperature is ND, route of measurement is not required. Please update "Route of measurement" and "If Other, specify" fields accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Sep 2020 02:08:59
Query 'Per CDM: Since Temperature is ND, route of measurement is not required. Please update "Route of measurement" and "If Other, specify" fields accordingly.' answered with 'updated' (Site from DM).	Brad Killebrew (b) (4)	08 Sep 2020 17:14:48
User entered empty; reason for change Data Entry Error	Brad Killebrew (b) (4)	08 Sep 2020 17:14:43
User opened query 'Per CDM: Since Temperature is ND, route of measurement is not required. Please update "Route of measurement" and "If Other, specify" fields accordingly.' (Site from DM).	(b) (4), (b) (6)	05 Sep 2020 11:10:20
User entered 'Other (Other)' reason for change: Data Entry Error	Leah Corts (b) (4)	18 Aug 2020 13:44:25
User entered 'Oral (Oral)'	Leah Corts (b) (4)	28 Jul 2020 23:56:44

US3122085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	18 Aug 2020 13:44:25
User entered empty.	Leah Corts (b) (4)	28 Jul 2020 23:56:44

US3122085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	18 Aug 2020 13:44:25
User entered '49'	Leah Corts (b) (4)	28 Jul 2020 23:56:44

US3122085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered 'bpm'	System	28 Jul 2020 23:56:44

US3122085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	18 Aug 2020 13:44:25
User entered '16'	Leah Corts (b) (4)	28 Jul 2020 23:56:44

US3122085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered 'breaths/min'	System	28 Jul 2020 23:56:44

US3122085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	18 Aug 2020 13:44:25
User entered '127'	Leah Corts (b) (4)	28 Jul 2020 23:56:44

US3122085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered 'mmHg'	System	28 Jul 2020 23:56:44

US3122085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	18 Aug 2020 13:44:25
User entered '82'	Leah Corts (b) (4)	28 Jul 2020 23:56:44

US3122085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User entered 'mmHg'	System	28 Jul 2020 23:56:44

US3122085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51

US3122085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51

US3122085

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:22:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	28 Jul 2020 23:56:57

US3122085

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:22:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	08 Sep 2020 03:50:15
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	28 Aug 2020 21:18:40
User entered '28 Jul 2020'	Leah Corts (b) (4)	28 Jul 2020 23:56:57

US3122085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'No (N)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:41:29

US3122085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'No (N)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:41:29

US3122085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:22:03

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)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'No (N)'	Brad Killebrew (b) (4)	31 Jul 2020 20:41:29

US3122085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:22:03

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)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'No (N)'	Brad Killebrew (b) (4)	31 Jul 2020 20:41:29

US3122085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'No (N)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:41:29

US3122085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:22:03

[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)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'No (N)'	Brad Killebrew (b) (4)	31 Jul 2020 20:41:29

US3122085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:22:03

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)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'No (N)'	Brad Killebrew (b) (4)	31 Jul 2020 20:41:29

US3122085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:22:03

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)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'No (N)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:41:29

US3122085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:22:03

[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)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'No (N)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:41:29

US3122085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:22:03

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)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'No (N)'	Brad Killebrew (b) (4)	31 Jul 2020 20:41:29

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:22:03

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)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'No (N)'	Brad Killebrew (b) (4)	31 Jul 2020 20:41:29

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:22:03

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:41:29

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:22:03

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Retired'	Brad Killebrew (b) (4)	31 Jul 2020 20:41:29

US3122085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:22:03

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:41:29

US3122085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '0'	Brad Killebrew (b) (4)	31 Jul 2020 20:41:29

US3122085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:22:03

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)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '0'	Brad Killebrew (b) (4)	31 Jul 2020 20:41:29

US3122085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:22:03

[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)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:41:29

US3122085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:22:03

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)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '0'	Brad Killebrew (b) (4)	31 Jul 2020 20:41:29

US3122085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'I'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:41:29

US3122085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:22:03

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '0'	Brad Killebrew (b) (4)	31 Jul 2020 20:41:29

US3122085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:22:03

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered empty.	Brad Killebrew (b) (4)	31 Jul 2020 20:41:29

US3122085

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:22:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	28 Jul 2020 23:57:15

US3122085

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '28 Jul 2020'	(b) (4) Leah Corts (b) (4)	28 Jul 2020 23:57:15

US3122085

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Clinic (Clinic)'	(b) (4) Leah Corts (b) (4)	28 Jul 2020 23:57:15

US3122085

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:22:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User entered 'VISIT1'	System	28 Jul 2020 23:57:15

US3122085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '28 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT(b) (4)	28 Jul 2020 19:44:14

US3122085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:22:03

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 01:09:50
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:09:50
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Jul 2020 19:44:14
User entered '184101' (non-conformant).	RWS_ENDPOINT ENDPOINT(b) (4)	28 Jul 2020 19:44:14

US3122085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT(b) (4)	28 Jul 2020 19:44:14

US3122085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'No (N)'	(b) (4) Aubrey Farray (b) (4)	17 Aug 2020 20:17:35

US3122085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	Aubrey Farray (b) (4)	17 Aug 2020 20:17:35

US3122085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'No (N)'	(b) (4) Aubrey Farrey (b) (4) (b) (4)	17 Aug 2020 20:17:35

US3122085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:22:03

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'No (N)'	(b) (4) Aubrey Farrey (b) (4) (b) (4)	17 Aug 2020 20:17:35

US3122085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:22:03

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'No (N)'	(b) (4) Aubrey Farrah (b) (4) (b) (4)	17 Aug 2020 20:17:35

US3122085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:22:03

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User closed query 'Per CDM: As ND is recorded for Weight and Height. Please remove units for Height and Weight.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:44:52
Query 'Per CDM: As ND is recorded for Weight and Height. Please remove units for Height and Weight.' answered with 'corrected' (Site from DM).	Leah Corts (b) (4)	10 Sep 2020 14:38:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Leah Corts (b) (4)	10 Sep 2020 14:38:47
User opened query 'Per CDM: As ND is recorded for Weight and Height. Please remove units for Height and Weight.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 15:05:40
User entered missing code ND - Not Done; reason for change Data Entry Error	Leah Corts (b) (4)	18 Aug 2020 13:44:43
User entered '70' in	Leah Corts (b) (4)	29 Jul 2020 00:00:08

US3122085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:22:03

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	10 Sep 2020 14:39:01
User entered missing code ND - Not Done; reason for change Data Entry Error	Leah Corts (b) (4)	18 Aug 2020 13:44:43
User entered '239' lb	Leah Corts (b) (4)	29 Jul 2020 00:00:08

US3122085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:22:03

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User closed query 'Per CDM: As ND is recorded for Weight and Height. Please remove units for Height and Weight.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:44:52
Query 'Per CDM: As ND is recorded for Weight and Height. Please remove units for Height and Weight.' answered with 'corrected' (Site from DM).	Leah Corts (b) (4)	10 Sep 2020 14:38:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Leah Corts (b) (4)	10 Sep 2020 14:38:47
User opened query 'Per CDM: As ND is recorded for Weight and Height. Please remove units for Height and Weight.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 15:05:40
User entered missing code ND - Not Done; reason for change Data Entry Error	Leah Corts (b) (4)	18 Aug 2020 13:44:43
User entered '70' in	Leah Corts (b) (4)	29 Jul 2020 00:00:08

US3122085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:22:03

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	10 Sep 2020 14:39:01
User entered missing code ND - Not Done; reason for change Data Entry Error	Leah Corts (b) (4)	18 Aug 2020 13:44:43
User entered '239' lb	Leah Corts (b) (4)	29 Jul 2020 00:00:08

US3122085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User accepted default value 'Pre-Dose (PREDOSE)'	Leah Corts (b) (4)	29 Jul 2020 00:00:08

US3122085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 00:00:08

US3122085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '28 Jul 2020'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 00:00:08

US3122085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '15:06'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 00:00:08

US3122085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User entered '28 Jul 2020 15:06'	System	29 Jul 2020 00:00:08

US3122085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '98.2' F	(b) (4) Leah Corts (b) (4)	29 Jul 2020 00:00:08

US3122085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Oral (Oral)'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 00:00:08

US3122085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered empty.	(b) (4) Leah Corts (b) (4)	29 Jul 2020 00:00:08

US3122085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '49'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 00:00:08

US3122085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User entered 'bpm'	System	29 Jul 2020 00:00:08

US3122085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '16'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 00:00:08

US3122085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User entered 'breaths/min'	System	29 Jul 2020 00:00:08

US3122085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '127'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 00:00:08

US3122085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User entered 'mmHg'	System	29 Jul 2020 00:00:08

US3122085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '82'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 00:00:08

US3122085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User entered 'mmHg'	System	29 Jul 2020 00:00:08

US3122085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:22:03

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User closed query 'Per CDM: As ND is recorded for Weight and Height. Please remove units for Height and Weight.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:44:52
Query 'Per CDM: As ND is recorded for Weight and Height. Please remove units for Height and Weight.' answered with 'corrected' (Site from DM).	Leah Corts (b) (4)	10 Sep 2020 14:38:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Leah Corts (b) (4)	10 Sep 2020 14:38:47
User opened query 'Per CDM: As ND is recorded for Weight and Height. Please remove units for Height and Weight.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 15:05:40
User entered missing code ND - Not Done; reason for change Data Entry Error	Leah Corts (b) (4)	18 Aug 2020 13:44:43
User entered '70' in	Leah Corts (b) (4)	29 Jul 2020 00:00:08

US3122085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:22:03

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	10 Sep 2020 14:39:01
User entered missing code ND - Not Done; reason for change Data Entry Error	Leah Corts (b) (4)	18 Aug 2020 13:44:43
User entered '239' lb	Leah Corts (b) (4)	29 Jul 2020 00:00:08

US3122085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User accepted default value 'Post-Dose (POSTDOSE)'	Leah Corts (b) (4)	29 Jul 2020 00:00:08

US3122085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 00:00:08

US3122085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '28 Jul 2020'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 00:00:08

US3122085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User closed query 'Per CDM: The treatment time on the Exposure CRF is 16:45. The Vital Signs Post Dose Time of Assessment is 17:12. Per protocol the post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:23:53
Query 'Per CDM: The treatment time on the Exposure CRF is 16:45. The Vital Signs Post Dose Time of Assessment is 17:12. Per protocol the post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed. ' answered with 'done 27 min past dose, this is not CS. Patient is stable' (Site from DM).	Leah Corts (b) (4)	30 Sep 2020 19:07:20
User entered '17:12' reason for change: Data Entry Error	Leah Corts (b) (4)	21 Aug 2020 16:28:58
User entered '16:45' reason for change: Data Entry Error	Leah Corts (b) (4)	21 Aug 2020 16:28:36
User opened query 'Per CDM: The treatment time on the Exposure CRF is 16:45. The Vital Signs Post Dose Time of Assessment is 17:12. Per protocol the post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed. ' (Site from DM).	Ipsita Abalokita (b) (4) (b) (4)	06 Aug 2020 22:27:47
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	Ipsita Abalokita (b) (4) (b) (4)	06 Aug 2020 22:27:02
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Correct as is' (Site from System).	Brad Killebrew (b) (4)	31 Jul 2020 19:55:53
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	29 Jul 2020 00:02:05

US3122085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
User entered '17:12'	Leah Corts (b) (4)	29 Jul 2020 00:00:08

US3122085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User entered '28 Jul 2020 17:12'	System	21 Aug 2020 16:28:58
User entered '28 Jul 2020 16:45'	System	21 Aug 2020 16:28:36
User entered '28 Jul 2020 17:12'	System	29 Jul 2020 00:00:08

US3122085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '97.7' F	(b) (4) Leah Corts (b) (4)	29 Jul 2020 00:00:08

US3122085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Oral (Oral)'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 00:00:08

US3122085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered empty.	(b) (4) Leah Corts (b) (4)	29 Jul 2020 00:00:08

US3122085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '50'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 00:00:08

US3122085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User entered 'bpm'	System	29 Jul 2020 00:00:08

US3122085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '18'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 00:00:08

US3122085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User entered 'breaths/min'	System	29 Jul 2020 00:00:08

US3122085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '142'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 00:00:08

US3122085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User entered 'mmHg'	System	29 Jul 2020 00:00:08

US3122085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '86'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 00:00:08

US3122085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User entered 'mmHg'	System	29 Jul 2020 00:00:08

US3122085

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:22:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 19:56:39

US3122085

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:22:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '28 Jul 2020'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 19:56:39

US3122085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 00:02:05

US3122085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered empty.	(b) (4) Leah Corts (b) (4)	29 Jul 2020 00:02:05

US3122085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered empty.	Leah Corts (b) (4)	29 Jul 2020 00:02:05

US3122085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User entered 'MRNA-1273 OR PLACEBO'	System	29 Jul 2020 00:02:05

US3122085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '28 Jul 2020'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 00:02:05

US3122085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '16:45'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 00:02:05

US3122085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User entered '28 Jul 2020 16:45'	System	29 Jul 2020 00:02:05

US3122085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 00:02:05

US3122085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User entered 'ONCE'	System	29 Jul 2020 00:02:05

US3122085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User entered 'INTRAMUSCULAR'	System	29 Jul 2020 00:02:05

US3122085

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:22:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 00:02:42

US3122085

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:22:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '28 Jul 2020'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 00:02:42

US3122085

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:22:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '16:22'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 00:02:42

US3122085

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User entered '28 Jul 2020 16:22'	System	29 Jul 2020 00:02:42

US3122085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:22:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '28 Jul 2020'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 00:03:00

US3122085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:22:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Leah Corts (b) (4)	29 Jul 2020 00:03:00

US3122085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:22:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 00:03:00

US3122085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:22:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '16:28'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 00:03:00

US3122085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:22:03

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User entered '28 Jul 2020 16:28'	System	29 Jul 2020 00:03:00

US3122085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:22:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Leah Corts (b) (4)	29 Jul 2020 00:03:00

US3122085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:22:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 00:03:00

US3122085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:22:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered empty.	(b) (4) Leah Corts (b) (4)	29 Jul 2020 00:03:00

US3122085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:22:03

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User entered empty.	System	29 Jul 2020 00:03:00

US3122085

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	07 Aug 2020 22:23:11

US3122085

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User entered 'I'	System	07 Aug 2020 22:23:11

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '28 Jul 2020 17:05'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '28 Jul 2020 19:35'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-28T22:22:14', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '8edbee9c-8925-44cf-a738-d54f58c2468f' User entered 'Yes (Y)'	System	29 Jul 2020 02:23:22
	System	29 Jul 2020 02:23:22

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-28T22:22:57', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '8edbee9c-8925-44cf-a738-d54f58c2468f' User entered '96.7'	System	29 Jul 2020 02:23:22
	System	29 Jul 2020 02:23:22

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-28T22:23:02', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '8edbee9c-8925-44cf-a738-d54f58c2468f' User entered 'No (N)'	System	29 Jul 2020 02:23:22
	System	29 Jul 2020 02:23:22

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-28T22:23:21', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '8edbee9c-8925-44cf-a738-d54f58c2468f' User entered '28 Jul 2020 22:23'	System	29 Jul 2020 02:23:22
	System	29 Jul 2020 02:23:22

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '28 Jul 2020 20:30'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '29 Jul 2020 11:59'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered 'Day 2'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:22:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-29T22:07:10', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '8b91fa69-48de-4079-9ef4-826afc21cfaf' User entered 'Yes (Y)'	System	30 Jul 2020 02:07:42
	System	30 Jul 2020 02:07:42

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:22:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-29T22:07:21', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '8b91fa69-48de-4079-9ef4-826afc21cfaf' User entered '97.1'	System	30 Jul 2020 02:07:42
	System	30 Jul 2020 02:07:42

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-29T22:07:28', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '8b91fa69-48de-4079-9ef4-826afc21cfaf' User entered 'No (N)'	System	30 Jul 2020 02:07:42
	System	30 Jul 2020 02:07:42

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:22:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-29T22:07:38', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '8b91fa69-48de-4079-9ef4-826afc21cfaf' User entered '29 Jul 2020 22:07'	System	30 Jul 2020 02:07:42
	System	30 Jul 2020 02:07:42

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '29 Jul 2020 12:00'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered 'Day 3'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:22:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-30T21:45:59', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '80bfe093-0b53-44b8-adda-71a0d1dfef98'	System	31 Jul 2020 01:46:39
User entered 'Yes (Y)'	System	31 Jul 2020 01:46:39

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:22:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-30T21:46:08', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '80bfe093-0b53-44b8-adda-71a0d1dfef98' User entered '96.3'	System	31 Jul 2020 01:46:39
	System	31 Jul 2020 01:46:39

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-30T21:46:15', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '80bfe093-0b53-44b8-adda-71a0d1dfef98'	System	31 Jul 2020 01:46:39
User entered 'No (N)'	System	31 Jul 2020 01:46:39

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:22:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-30T21:46:37', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '80bfe093-0b53-44b8-adda-71a0d1dfef98'	System	31 Jul 2020 01:46:39
User entered '30 Jul 2020 21:46'	System	31 Jul 2020 01:46:39

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered 'Day 4'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:22:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-31T22:28:20', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '6365bb1b-bb86-4aee-a4f5-6fde0dec74a7' User entered 'Yes (Y)'	System	12 Aug 2020 04:33:54
	System	12 Aug 2020 04:33:54

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:22:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-31T22:28:29', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '6365bb1b-bb86-4aee-a4f5-6fde0dec74a7' User entered '96.1'	System	12 Aug 2020 04:33:54
	System	12 Aug 2020 04:33:54

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-31T22:28:33', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '6365bb1b-bb86-4aee-a4f5-6fde0dec74a7'	System	12 Aug 2020 04:33:54
User entered 'No (N)'	System	12 Aug 2020 04:33:54

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:22:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-31T22:28:40', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '6365bb1b-bb86-4aee-a4f5-6fde0dec74a7' User entered '31 Jul 2020 22:28'	System	12 Aug 2020 04:33:54
	System	12 Aug 2020 04:33:54

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered 'Day 5'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:22:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-01T21:51:23', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '088fa63f-df6b-4ac6-81bb-785eeaa68389' User entered 'Yes (Y)'	System	12 Aug 2020 04:33:55
	System	12 Aug 2020 04:33:55

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:22:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-01T21:51:32', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '088fa63f-df6b-4ac6-81bb-785eeaa68389' User entered '96.7'	System	12 Aug 2020 04:33:55
	System	12 Aug 2020 04:33:55

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-01T21:51:37', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '088fa63f-df6b-4ac6-81bb-785eeaa68389'	System	12 Aug 2020 04:33:55
User entered 'No (N)'	System	12 Aug 2020 04:33:55

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:22:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-01T21:51:42', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '088fa63f-df6b-4ac6-81bb-785eeaa68389' User entered '01 Aug 2020 21:51'	System	12 Aug 2020 04:33:55
	System	12 Aug 2020 04:33:55

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered 'Day 6'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:22:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-03T00:38:08', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '56257f73-6ae4-4241-8c72-08228508734d' User entered 'Yes (Y)'	System	12 Aug 2020 04:33:57
	System	12 Aug 2020 04:33:57

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:22:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-03T00:38:48', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '56257f73-6ae4-4241-8c72-08228508734d' User entered '96.5'	System	12 Aug 2020 04:33:57
	System	12 Aug 2020 04:33:57

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-03T00:38:51', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '56257f73-6ae4-4241-8c72-08228508734d' User entered 'No (N)'	System	12 Aug 2020 04:33:57
	System	12 Aug 2020 04:33:57

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:22:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-03T00:38:56', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '56257f73-6ae4-4241-8c72-08228508734d' User entered '03 Aug 2020 00:38'	System	12 Aug 2020 04:33:57
	System	12 Aug 2020 04:33:57

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered 'Day 7'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:22:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-03T23:03:51', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'ee584d4b-6145-49c0-8d7c-8aeced303591' User entered 'Yes (Y)'	System	12 Aug 2020 04:33:58
	System	12 Aug 2020 04:33:58

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:22:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-03T23:04:00', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'ee584d4b-6145-49c0-8d7c-8aeced303591' User entered '97.6'	System	12 Aug 2020 04:33:58
	System	12 Aug 2020 04:33:58

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-03T23:04:03', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'ee584d4b-6145-49c0-8d7c-8aeced303591'	System	12 Aug 2020 04:33:58
User entered 'No (N)'	System	12 Aug 2020 04:33:58

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:22:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-03T23:04:09', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'ee584d4b-6145-49c0-8d7c-8aeced303591'	System	12 Aug 2020 04:33:58
User entered '03 Aug 2020 23:04'	System	12 Aug 2020 04:33:58

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

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)	27 Mar 2021 19:34:41

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '28 Jul 2020 17:05'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '28 Jul 2020 19:35'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-28T22:23:33', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '62806a96-04cf-47f0-8e78-9379154fbcd'	System	29 Jul 2020 02:24:30
User entered 'None (1)'	System	29 Jul 2020 02:24:30

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-28T22:23:37', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '62806a96-04cf-47f0-8e78-9379154fbcd'	System	29 Jul 2020 02:24:30
User entered 'No (N)'	System	29 Jul 2020 02:24:30

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-28T22:23:42', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '62806a96-04cf-47f0-8e78-9379154fbcd'	System	29 Jul 2020 02:24:30
User entered 'No (N)'	System	29 Jul 2020 02:24:30

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-28T22:24:16', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '62806a96-04cf-47f0-8e78-9379154fbcd'	System	29 Jul 2020 02:24:30
User entered 'None (1)'	System	29 Jul 2020 02:24:30

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-28T22:24:27', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '62806a96-04cf-47f0-8e78-9379154fbcd'	System	29 Jul 2020 02:24:30
User entered '28 Jul 2020 22:24'	System	29 Jul 2020 02:24:30

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '28 Jul 2020 20:30'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '29 Jul 2020 11:59'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered 'Day 2'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:22:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-29T22:08:33', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '31ee15fe-0af1-4a22-ae74-f152b3e9a1a5'	System	30 Jul 2020 02:09:30
User entered 'None (1)'	System	30 Jul 2020 02:09:30

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:22:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-29T22:08:38', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '31ee15fe-0af1-4a22-ae74-f152b3e9a1a5'	System	30 Jul 2020 02:09:30
User entered 'No (N)'	System	30 Jul 2020 02:09:30

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-29T22:08:43', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '31ee15fe-0af1-4a22-ae74-f152b3e9a1a5' User entered 'No (N)'	System	30 Jul 2020 02:09:30
	System	30 Jul 2020 02:09:30

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:22:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-29T22:09:17', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '31ee15fe-0af1-4a22-ae74-f152b3e9a1a5'	System	30 Jul 2020 02:09:30
User entered 'None (1)'	System	30 Jul 2020 02:09:30

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:22:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-29T22:09:29', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '31ee15fe-0af1-4a22-ae74-f152b3e9a1a5'	System	30 Jul 2020 02:09:30
User entered '29 Jul 2020 22:09'	System	30 Jul 2020 02:09:30

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '29 Jul 2020 12:00'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered 'Day 3'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:22:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-30T21:46:52', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'fcf5fbbb-eef9-40c9-9e97-d1e74fd0bc4c' User entered 'None (1)'	System	31 Jul 2020 01:47:39
	System	31 Jul 2020 01:47:39

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:22:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-30T21:46:57', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'fcf5fbbb-eef9-40c9-9e97-d1e74fd0bc4c' User entered 'No (N)'	System	31 Jul 2020 01:47:39
	System	31 Jul 2020 01:47:39

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-30T21:47:05', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'fcf5fbbb-eef9-40c9-9e97-d1e74fd0bc4c' User entered 'No (N)'	System	31 Jul 2020 01:47:39
	System	31 Jul 2020 01:47:39

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:22:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-30T21:47:16', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'fcf5fbbb-eef9-40c9-9e97-d1e74fd0bc4c'	System	31 Jul 2020 01:47:39
User entered 'None (1)'	System	31 Jul 2020 01:47:39

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:22:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-30T21:47:35', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'fcf5fbbb-eef9-40c9-9e97-d1e74fd0bc4c' User entered '30 Jul 2020 21:47'	System	31 Jul 2020 01:47:39
	System	31 Jul 2020 01:47:39

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered 'Day 4'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:22:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-31T22:28:46', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '67d89024-2496-4b4f-86fa-c210009777ba'	System	12 Aug 2020 04:33:54
User entered 'None (1)'	System	12 Aug 2020 04:33:54

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:22:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-31T22:28:50', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '67d89024-2496-4b4f-86fa-c210009777ba' User entered 'No (N)'	System	12 Aug 2020 04:33:54
	System	12 Aug 2020 04:33:54

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-31T22:28:54', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '67d89024-2496-4b4f-86fa-c210009777ba' User entered 'No (N)'	System	12 Aug 2020 04:33:54
	System	12 Aug 2020 04:33:54

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:22:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-31T22:29:05', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '67d89024-2496-4b4f-86fa-c210009777ba' User entered 'None (1)'	System	12 Aug 2020 04:33:54
	System	12 Aug 2020 04:33:54

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:22:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-31T22:29:11', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '67d89024-2496-4b4f-86fa-c210009777ba' User entered '31 Jul 2020 22:29'	System	12 Aug 2020 04:33:54
	System	12 Aug 2020 04:33:54

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered 'Day 5'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:22:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-01T21:51:52', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'adafb24c-8439-4251-ae87-3244da60cabc' User entered 'None (1)'	System	12 Aug 2020 04:33:56
	System	12 Aug 2020 04:33:56

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:22:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-01T21:51:58', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'adafb24c-8439-4251-ae87-3244da60cab'	System	12 Aug 2020 04:33:56
User entered 'No (N)'	System	12 Aug 2020 04:33:56

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-01T21:52:04', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'adafb24c-8439-4251-ae87-3244da60cab'	System	12 Aug 2020 04:33:56
User entered 'No (N)'	System	12 Aug 2020 04:33:56

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:22:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-01T21:52:20', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'adafb24c-8439-4251-ae87-3244da60cabc' User entered 'None (1)'	System	12 Aug 2020 04:33:56
	System	12 Aug 2020 04:33:56

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:22:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-01T21:52:25', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'adafb24c-8439-4251-ae87-3244da60cab'	System	12 Aug 2020 04:33:56
User entered '01 Aug 2020 21:52'	System	12 Aug 2020 04:33:56

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered 'Day 6'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:22:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-03T00:39:14', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'b0a088da-4e8a-43ed-9859-c9c9ed7ab500'	System	12 Aug 2020 04:33:57
User entered 'None (1)'	System	12 Aug 2020 04:33:57

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:22:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-03T00:39:18', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'b0a088da-4e8a-43ed-9859-c9c9ed7ab500'	System	12 Aug 2020 04:33:57
User entered 'No (N)'	System	12 Aug 2020 04:33:57

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-03T00:39:23', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'b0a088da-4e8a-43ed-9859-c9c9ed7ab500' User entered 'No (N)'	System	12 Aug 2020 04:33:57
	System	12 Aug 2020 04:33:57

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:22:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-03T00:39:36', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'b0a088da-4e8a-43ed-9859-c9c9ed7ab500'	System	12 Aug 2020 04:33:57
User entered 'None (1)'	System	12 Aug 2020 04:33:57

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:22:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-03T00:39:39', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'b0a088da-4e8a-43ed-9859-c9c9ed7ab500'	System	12 Aug 2020 04:33:57
User entered '03 Aug 2020 00:39'	System	12 Aug 2020 04:33:57

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered 'Day 7'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:22:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-03T23:04:16', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '5ca14c6d-18d0-4c60-adde-9612b53f3d0e' User entered 'None (1)'	System	12 Aug 2020 04:33:59
	System	12 Aug 2020 04:33:59

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:22:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-03T23:04:20', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '5ca14c6d-18d0-4c60-adde-9612b53f3d0e' User entered 'No (N)'	System	12 Aug 2020 04:33:59
	System	12 Aug 2020 04:33:59

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-03T23:04:23', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '5ca14c6d-18d0-4c60-adde-9612b53f3d0e' User entered 'No (N)'	System	12 Aug 2020 04:33:59
	System	12 Aug 2020 04:33:59

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:22:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-03T23:04:28', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '5ca14c6d-18d0-4c60-adde-9612b53f3d0e' User entered 'None (1)'	System	12 Aug 2020 04:33:59
	System	12 Aug 2020 04:33:59

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:22:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-03T23:04:34', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '5ca14c6d-18d0-4c60-adde-9612b53f3d0e' User entered '03 Aug 2020 23:04'	System	12 Aug 2020 04:33:59
	System	12 Aug 2020 04:33:59

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

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)	27 Mar 2021 19:34:41

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '28 Jul 2020 17:05'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '28 Jul 2020 19:35'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-28T22:24:35', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '987ce594-35d7-43f9-b7d9-7338f959bff1' User entered 'None (0)'	System	29 Jul 2020 02:25:18
	System	29 Jul 2020 02:25:18

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-28T22:24:44', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '987ce594-35d7-43f9-b7d9-7338f959bff1' User entered 'None (0)'	System	29 Jul 2020 02:25:18
	System	29 Jul 2020 02:25:18

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-28T22:24:47', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '987ce594-35d7-43f9-b7d9-7338f959bff1' User entered 'None (0)'	System	29 Jul 2020 02:25:18
	System	29 Jul 2020 02:25:18

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-28T22:24:53', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '987ce594-35d7-43f9-b7d9-7338f959bff1' User entered 'None (0)'	System	29 Jul 2020 02:25:18
	System	29 Jul 2020 02:25:18

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-28T22:24:56', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '987ce594-35d7-43f9-b7d9-7338f959bff1' User entered 'None (0)'	System	29 Jul 2020 02:25:18
	System	29 Jul 2020 02:25:18

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-28T22:24:58', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '987ce594-35d7-43f9-b7d9-7338f959bff1' User entered 'None (0)'	System	29 Jul 2020 02:25:18
	System	29 Jul 2020 02:25:18

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

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)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-28T22:25:05', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '987ce594-35d7-43f9-b7d9-7338f959bff1'	System	29 Jul 2020 02:25:18
User entered 'No (N)'	System	29 Jul 2020 02:25:18

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-28T22:25:15', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '987ce594-35d7-43f9-b7d9-7338f959bff1' User entered '28 Jul 2020 22:25'	System	29 Jul 2020 02:25:18
	System	29 Jul 2020 02:25:18

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '28 Jul 2020 20:30'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '29 Jul 2020 11:59'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered 'Day 2'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:22:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-29T22:09:41', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '5f2c06bf-35f3-4384-949b-8651518bc072' User entered 'None (0)'	System	30 Jul 2020 02:10:34
	System	30 Jul 2020 02:10:34

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:22:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-29T22:10:02', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '5f2c06bf-35f3-4384-949b-8651518bc072'	System	30 Jul 2020 02:10:34
User entered 'No interference with activity (1)'	System	30 Jul 2020 02:10:34

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:22:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-29T22:10:07', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '5f2c06bf-35f3-4384-949b-8651518bc072' User entered 'None (0)'	System	30 Jul 2020 02:10:34
	System	30 Jul 2020 02:10:34

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:22:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-29T22:10:13', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '5f2c06bf-35f3-4384-949b-8651518bc072' User entered 'None (0)'	System	30 Jul 2020 02:10:34
	System	30 Jul 2020 02:10:34

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:22:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-29T22:10:17', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '5f2c06bf-35f3-4384-949b-8651518bc072' User entered 'None (0)'	System	30 Jul 2020 02:10:34
	System	30 Jul 2020 02:10:34

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:22:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-29T22:10:20', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '5f2c06bf-35f3-4384-949b-8651518bc072' User entered 'None (0)'	System	30 Jul 2020 02:10:34
	System	30 Jul 2020 02:10:34

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:22:03

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)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-29T22:10:25', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '5f2c06bf-35f3-4384-949b-8651518bc072'	System	30 Jul 2020 02:10:34
User entered 'No (N)'	System	30 Jul 2020 02:10:34

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:22:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-29T22:10:32', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '5f2c06bf-35f3-4384-949b-8651518bc072'	System	30 Jul 2020 02:10:34
User entered '29 Jul 2020 22:10'	System	30 Jul 2020 02:10:34

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '29 Jul 2020 12:00'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered 'Day 3'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:22:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-30T21:47:56', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '17479829-4517-4f77-b0fc-60698a8e565c'	System	31 Jul 2020 01:49:11
User entered 'No interference with activity (1)'	System	31 Jul 2020 01:49:11

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:22:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-30T21:48:07', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '17479829-4517-4f77-b0fc-60698a8e565c'	System	31 Jul 2020 01:49:11
User entered 'No interference with activity (1)'	System	31 Jul 2020 01:49:11

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:22:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-30T21:48:20', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '17479829-4517-4f77-b0fc-60698a8e565c' User entered 'None (0)'	System	31 Jul 2020 01:49:11
	System	31 Jul 2020 01:49:11

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:22:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-30T21:48:26', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '17479829-4517-4f77-b0fc-60698a8e565c' User entered 'None (0)'	System	31 Jul 2020 01:49:11
	System	31 Jul 2020 01:49:11

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:22:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-30T21:48:34', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '17479829-4517-4f77-b0fc-60698a8e565c' User entered 'None (0)'	System	31 Jul 2020 01:49:11
	System	31 Jul 2020 01:49:11

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:22:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-30T21:48:42', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '17479829-4517-4f77-b0fc-60698a8e565c'	System	31 Jul 2020 01:49:11
User entered 'No interference with activity (1)'	System	31 Jul 2020 01:49:11

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:22:03

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)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-30T21:48:50', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '17479829-4517-4f77-b0fc-60698a8e565c' User entered 'No (N)'	System	31 Jul 2020 01:49:11
	System	31 Jul 2020 01:49:11

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:22:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-30T21:49:08', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '17479829-4517-4f77-b0fc-60698a8e565c' User entered '30 Jul 2020 21:49'	System	31 Jul 2020 01:49:11
	System	31 Jul 2020 01:49:11

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered 'Day 4'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:22:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-31T22:29:17', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'e46f646a-812e-4fef-8c86-e691d281de44'	System	12 Aug 2020 04:33:55
User entered 'None (0)'	System	12 Aug 2020 04:33:55

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:22:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-31T22:29:21', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'e46f646a-812e-4fef-8c86-e691d281de44' User entered 'None (0)'	System	12 Aug 2020 04:33:55
	System	12 Aug 2020 04:33:55

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:22:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-31T22:29:25', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'e46f646a-812e-4fef-8c86-e691d281de44' User entered 'None (0)'	System	12 Aug 2020 04:33:55
	System	12 Aug 2020 04:33:55

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:22:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-31T22:29:28', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'e46f646a-812e-4fef-8c86-e691d281de44' User entered 'None (0)'	System	12 Aug 2020 04:33:55
	System	12 Aug 2020 04:33:55

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:22:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-31T22:29:32', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'e46f646a-812e-4fef-8c86-e691d281de44' User entered 'None (0)'	System	12 Aug 2020 04:33:55
	System	12 Aug 2020 04:33:55

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:22:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-31T22:29:35', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'e46f646a-812e-4fef-8c86-e691d281de44' User entered 'None (0)'	System	12 Aug 2020 04:33:55
	System	12 Aug 2020 04:33:55

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:22:03

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)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-31T22:29:41', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'e46f646a-812e-4fef-8c86-e691d281de44'	System	12 Aug 2020 04:33:55
User entered 'No (N)'	System	12 Aug 2020 04:33:55

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:22:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-07-31T22:29:46', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'e46f646a-812e-4fef-8c86-e691d281de44'	System	12 Aug 2020 04:33:55
User entered '31 Jul 2020 22:29'	System	12 Aug 2020 04:33:55

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered 'Day 5'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:22:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-01T21:52:31', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '51ae03f2-e5b8-4499-8895-5d027e07bab3' User entered 'None (0)'	System	12 Aug 2020 04:33:56
	System	12 Aug 2020 04:33:56

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:22:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-01T21:52:36', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '51ae03f2-e5b8-4499-8895-5d027e07bab3' User entered 'None (0)'	System	12 Aug 2020 04:33:56
	System	12 Aug 2020 04:33:56

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:22:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-01T21:52:40', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '51ae03f2-e5b8-4499-8895-5d027e07bab3' User entered 'None (0)'	System	12 Aug 2020 04:33:56
	System	12 Aug 2020 04:33:56

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:22:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-01T21:52:44', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '51ae03f2-e5b8-4499-8895-5d027e07bab3' User entered 'None (0)'	System	12 Aug 2020 04:33:56
	System	12 Aug 2020 04:33:56

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:22:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-01T21:52:47', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '51ae03f2-e5b8-4499-8895-5d027e07bab3' User entered 'None (0)'	System	12 Aug 2020 04:33:56
	System	12 Aug 2020 04:33:56

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:22:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-01T21:52:49', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '51ae03f2-e5b8-4499-8895-5d027e07bab3' User entered 'None (0)'	System	12 Aug 2020 04:33:56
	System	12 Aug 2020 04:33:56

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:22:03

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)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-01T21:52:53', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '51ae03f2-e5b8-4499-8895-5d027e07bab3'	System	12 Aug 2020 04:33:56
User entered 'No (N)'	System	12 Aug 2020 04:33:56

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:22:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-01T21:52:57', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '51ae03f2-e5b8-4499-8895-5d027e07bab3' User entered '01 Aug 2020 21:52'	System	12 Aug 2020 04:33:56
	System	12 Aug 2020 04:33:56

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered 'Day 6'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:22:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-03T00:39:46', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '780726b2-fa4a-4a1d-b845-87518dedd0f8' User entered 'None (0)'	System	12 Aug 2020 04:33:58
	System	12 Aug 2020 04:33:58

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:22:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-03T00:39:52', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '780726b2-fa4a-4a1d-b845-87518dedd0f8' User entered 'None (0)'	System	12 Aug 2020 04:33:58
	System	12 Aug 2020 04:33:58

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:22:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-03T00:39:55', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '780726b2-fa4a-4a1d-b845-87518dedd0f8' User entered 'None (0)'	System	12 Aug 2020 04:33:58
	System	12 Aug 2020 04:33:58

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:22:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-03T00:39:59', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '780726b2-fa4a-4a1d-b845-87518dedd0f8' User entered 'None (0)'	System	12 Aug 2020 04:33:58
	System	12 Aug 2020 04:33:58

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:22:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-03T00:40:02', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '780726b2-fa4a-4a1d-b845-87518dedd0f8' User entered 'None (0)'	System	12 Aug 2020 04:33:58
	System	12 Aug 2020 04:33:58

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:22:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-03T00:40:04', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '780726b2-fa4a-4a1d-b845-87518dedd0f8' User entered 'None (0)'	System	12 Aug 2020 04:33:58
	System	12 Aug 2020 04:33:58

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:22:03

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)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-03T00:40:09', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '780726b2-fa4a-4a1d-b845-87518dedd0f8' User entered 'No (N)'	System	12 Aug 2020 04:33:58
	System	12 Aug 2020 04:33:58

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:22:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-03T00:40:12', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '780726b2-fa4a-4a1d-b845-87518dedd0f8'	System	12 Aug 2020 04:33:58
User entered '03 Aug 2020 00:40'	System	12 Aug 2020 04:33:58

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered 'Day 7'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:22:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-03T23:05:10', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'b9b5a259-8dc0-4d72-94d3-54c37559d840'	System	12 Aug 2020 04:33:59
User entered 'No interference with activity (1)'	System	12 Aug 2020 04:33:59

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:22:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-03T23:05:14', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'b9b5a259-8dc0-4d72-94d3-54c37559d840'	System	12 Aug 2020 04:33:59
User entered 'None (0)'	System	12 Aug 2020 04:33:59

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:22:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-03T23:05:17', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'b9b5a259-8dc0-4d72-94d3-54c37559d840' User entered 'None (0)'	System	12 Aug 2020 04:33:59
	System	12 Aug 2020 04:33:59

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:22:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-03T23:05:23', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'b9b5a259-8dc0-4d72-94d3-54c37559d840' User entered 'None (0)'	System	12 Aug 2020 04:33:59
	System	12 Aug 2020 04:33:59

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:22:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-03T23:05:27', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'b9b5a259-8dc0-4d72-94d3-54c37559d840' User entered 'None (0)'	System	12 Aug 2020 04:33:59
	System	12 Aug 2020 04:33:59

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:22:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-03T23:05:30', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'b9b5a259-8dc0-4d72-94d3-54c37559d840' User entered 'None (0)'	System	12 Aug 2020 04:33:59
	System	12 Aug 2020 04:33:59

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:22:03

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)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-03T23:05:33', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'b9b5a259-8dc0-4d72-94d3-54c37559d840'	System	12 Aug 2020 04:33:59
User entered 'No (N)'	System	12 Aug 2020 04:33:59

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:22:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-03T23:05:47', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'b9b5a259-8dc0-4d72-94d3-54c37559d840'	System	12 Aug 2020 04:33:59
User entered '03 Aug 2020 23:05'	System	12 Aug 2020 04:33:59

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 00:02:05

US3122085

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	12 Aug 2020 04:33:59
User entered 'Day 8'	System	12 Aug 2020 04:33:59

US3122085

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:22:03

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41

US3122085

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:22:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41

US3122085

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '04 Aug 2020 12:00'	System	12 Aug 2020 04:33:59

US3122085

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '05 Aug 2020 11:59'	System	12 Aug 2020 04:33:59

US3122085

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	12 Aug 2020 04:33:59
User entered 'Day 9'	System	12 Aug 2020 04:33:59

US3122085

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:22:03

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41

US3122085

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:22:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41

US3122085

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '05 Aug 2020 12:00'	System	12 Aug 2020 04:33:59

US3122085

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '06 Aug 2020 11:59'	System	12 Aug 2020 04:33:59

US3122085

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	12 Aug 2020 04:33:59
User entered 'Day 8'	System	12 Aug 2020 04:33:59

US3122085

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:22:03

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)	27 Mar 2021 19:34:41

US3122085

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:22:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41

US3122085

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '04 Aug 2020 12:00'	System	12 Aug 2020 04:33:59

US3122085

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '05 Aug 2020 11:59'	System	12 Aug 2020 04:33:59

US3122085

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	12 Aug 2020 04:33:59
User entered 'Day 9'	System	12 Aug 2020 04:33:59

US3122085

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:22:03

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)	27 Mar 2021 19:34:41

US3122085

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:22:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41

US3122085

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '05 Aug 2020 12:00'	System	12 Aug 2020 04:33:59

US3122085

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '06 Aug 2020 11:59'	System	12 Aug 2020 04:33:59

US3122085

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	07 Aug 2020 22:23:27

US3122085

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '06 Aug 2020'	(b) (4) Leah Corts (b) (4)	07 Aug 2020 22:23:27

US3122085

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Leah Corts (b) (4)	07 Aug 2020 22:23:27

US3122085

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered empty.	(b) (4) Leah Corts (b) (4)	07 Aug 2020 22:23:27

US3122085

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	07 Aug 2020 22:23:34

US3122085

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User entered 'I'	System	07 Aug 2020 22:23:34

US3122085

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	(b) (4) Aubrey Farrah (b) (4)	17 Aug 2020 20:17:51

US3122085

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '12 Aug 2020'	(b) (4) Aubrey Farray (b) (4)	17 Aug 2020 20:17:51

US3122085

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Aubrey Farray (b) (4) (b) (4)	17 Aug 2020 20:17:51

US3122085

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) Aubrey Farray (b) (4)	17 Aug 2020 20:17:51

US3122085

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	(b) (4) Aubrey Farrah (b) (4)	17 Aug 2020 20:18:05

US3122085

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:31:10
User entered 'I'	System	17 Aug 2020 20:18:05

US3122085

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:35:44
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	(b) (4) Aubrey Farray (b) (4) (b) (4)	19 Aug 2020 16:57:14

US3122085

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:35:44
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '19 Aug 2020'	(b) (4) Aubrey Farray (b) (4) (b) (4)	19 Aug 2020 16:57:14

US3122085

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:35:44
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Aubrey Farray (b) (4)	19 Aug 2020 16:57:14

US3122085

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:35:44
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	Aubrey Farray (b) (4)	19 Aug 2020 16:57:14

US3122085

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:35:44
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	(b) (4) Aubrey Farrey (b) (4) (b) (4)	19 Aug 2020 16:57:20

US3122085

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:35:44
User entered 'I'	System	19 Aug 2020 16:57:20

US3122085

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:22:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) Aubrey Farray (b) (4) (b) (4)	28 Aug 2020 21:18:40

US3122085

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '26 Aug 2020'	(b) (4) Aubrey Farray (b) (4) (b) (4)	28 Aug 2020 21:18:40

US3122085

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:22:03

[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 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Clinic (Clinic)'	(b) (4) Aubrey Farray (b) (4) (b) (4)	28 Aug 2020 21:18:40

US3122085

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:22:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User entered 'VISIT2'	System	28 Aug 2020 21:18:40

US3122085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User accepted default value 'Pre-Dose (PREDOSE)'	Aubrey Farray (b) (4) (b) (4)	28 Aug 2020 21:19:26

US3122085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) Aubrey Farray (b) (4) (b) (4)	28 Aug 2020 21:19:26

US3122085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '26 Aug 2020'	(b) (4) Aubrey Farray (b) (4)	28 Aug 2020 21:19:26

US3122085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '15:18'	(b) (4) Aubrey Farray (b) (4) (b) (4)	28 Aug 2020 21:19:26

US3122085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User entered '26 Aug 2020 15:18'	System	28 Aug 2020 21:19:26

US3122085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '98.2' F	(b) (4) Aubrey Farray (b) (4) (b) (4)	28 Aug 2020 21:19:26

US3122085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Oral (Oral)'	(b) (4) Aubrey Farray (b) (4) (b) (4)	28 Aug 2020 21:19:26

US3122085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered empty.	(b) (4) Aubrey Farrray (b) (4) (b) (4)	28 Aug 2020 21:19:26

US3122085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '54'	(b) (4) Aubrey Farray (b) (4) (b) (4)	28 Aug 2020 21:19:26

US3122085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User entered 'bpm'	System	28 Aug 2020 21:19:26

US3122085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '17'	(b) (4) Aubrey Farray (b) (4) (b) (4)	28 Aug 2020 21:19:26

US3122085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User entered 'breaths/min'	System	28 Aug 2020 21:19:26

US3122085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '117'	(b) (4) Aubrey Farrah (b) (4) (b) (4)	28 Aug 2020 21:19:26

US3122085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User entered 'mmHg'	System	28 Aug 2020 21:19:26

US3122085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '82'	(b) (4) Aubrey Farrey (b) (4) (b) (4)	28 Aug 2020 21:19:26

US3122085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User entered 'mmHg'	System	28 Aug 2020 21:19:26

US3122085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User accepted default value 'Post-Dose (POSTDOSE)'	Aubrey Farray (b) (4) (b) (4)	28 Aug 2020 21:19:26

US3122085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) Aubrey Farray (b) (4) (b) (4)	28 Aug 2020 21:19:26

US3122085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '26 Aug 2020'	(b) (4) Aubrey Farray (b) (4) (b) (4)	28 Aug 2020 21:19:26

US3122085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '17:12'	(b) (4) Aubrey Farray (b) (4) (b) (4)	28 Aug 2020 21:19:26

US3122085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User entered '26 Aug 2020 17:12'	System	28 Aug 2020 21:19:26

US3122085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '98.3' F	(b) (4) Aubrey Farray (b) (4) (b) (4)	28 Aug 2020 21:19:26

US3122085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Oral (Oral)'	(b) (4) Aubrey Farray (b) (4) (b) (4)	28 Aug 2020 21:19:26

US3122085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered empty.	(b) (4) Aubrey Farray (b) (4) (b) (4)	28 Aug 2020 21:19:26

US3122085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '57'	(b) (4) Aubrey Farray (b) (4) (b) (4)	28 Aug 2020 21:19:26

US3122085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User entered 'bpm'	System	28 Aug 2020 21:19:26

US3122085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '16'	(b) (4) Aubrey Farray (b) (4) (b) (4)	28 Aug 2020 21:19:26

US3122085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User entered 'breaths/min'	System	28 Aug 2020 21:19:26

US3122085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '129'	(b) (4) Aubrey Farray (b) (4) (b) (4)	28 Aug 2020 21:19:26

US3122085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User entered 'mmHg'	System	28 Aug 2020 21:19:26

US3122085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '86'	(b) (4) Aubrey Farray (b) (4) (b) (4)	28 Aug 2020 21:19:26

US3122085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User entered 'mmHg'	System	28 Aug 2020 21:19:26

US3122085

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:22:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) Aubrey Farray (b) (4) (b) (4)	28 Aug 2020 21:19:41

US3122085

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:22:03

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '26 Aug 2020'	(b) (4) Aubrey Farray (b) (4) (b) (4)	28 Aug 2020 21:19:41

US3122085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 21:04:53

US3122085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 21:04:53

US3122085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

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 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 21:04:53

US3122085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User entered 'MRNA-1273 OR PLACEBO'	System	26 Aug 2020 21:04:53

US3122085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 21:04:53

US3122085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '16:35'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 21:04:53

US3122085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User entered '26 Aug 2020 16:35'	System	26 Aug 2020 21:04:53

US3122085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 21:04:53

US3122085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User entered 'ONCE'	System	26 Aug 2020 21:04:53

US3122085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User entered 'INTRAMUSCULAR'	System	26 Aug 2020 21:04:53

US3122085

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:22:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) Aubrey Farrah (b) (4) (b) (4)	28 Aug 2020 21:20:03

US3122085

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:22:03

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 26AUG2020 is recorded under Visit 2 Day 29 visit in EDC, however 26AUG2020 is reported under UNSCHEDULED visit in PPD Central lab. Please confirm the correct visit and update EDC or PPD Central lab.	(b) (4), (b) (6)	18 Dec 2020 06:24:46
' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 26AUG2020 is recorded under Visit 2 Day 29 visit in EDC, however 26AUG2020 is reported under UNSCHEDULED visit in PPD Central lab. Please confirm the correct visit and update EDC or PPD Central lab.		17 Dec 2020 17:55:44
' answered with 'August 26th is the correct day of visit. Sending information to clinical team to update in ppd central lab. ' (Site from DM). User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 26AUG2020 is recorded under Visit 2 Day 29 visit in EDC, however 26AUG2020 is reported under UNSCHEDULED visit in PPD Central lab. Please confirm the correct visit and update EDC or PPD Central lab.		18 Nov 2020 06:43:23
' (Site from DM). User entered '26 Aug 2020'	Aubrey Farrah (b) (4) (b) (4)	28 Aug 2020 21:20:03

US3122085

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:22:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '15:55'	(b) (4) Aubrey Farrey (b) (4) (b) (4)	28 Aug 2020 21:20:03

US3122085

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User entered '26 Aug 2020 15:55'	System	28 Aug 2020 21:20:03

US3122085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:22:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Aubrey Farray (b) (4) (b) (4)	28 Aug 2020 21:20:23

US3122085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:22:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) Aubrey Farray (b) (4) (b) (4)	28 Aug 2020 21:20:23

US3122085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:22:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '16:55'	(b) (4) Aubrey Farray (b) (4) (b) (4)	28 Aug 2020 21:20:23

US3122085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User entered '26 Aug 2020 16:55'	System	28 Aug 2020 21:20:23

US3122085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:22:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Aubrey Farray (b) (4) (b) (4)	28 Aug 2020 21:20:23

US3122085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:22:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'No (N)'	(b) (4) Aubrey Farray (b) (4) (b) (4)	28 Aug 2020 21:20:23

US3122085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:22:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered empty.	(b) (4) Aubrey Farray (b) (4) (b) (4)	28 Aug 2020 21:20:23

US3122085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:22:03

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User entered empty.	System	28 Aug 2020 21:20:23

US3122085

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) Aubrey Farray (b) (4) (b) (4)	28 Aug 2020 21:20:29

US3122085

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User entered 'I'	System	28 Aug 2020 21:20:29

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	26 Aug 2020 21:04:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-26T17:06:47', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '225219c6-91ea-4658-b4db-de9e239e9090' User entered 'Yes (Y)'	System	26 Aug 2020 21:07:34
	System	26 Aug 2020 21:07:34

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-26T17:07:00', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '225219c6-91ea-4658-b4db-de9e239e9090' User entered '98.3'	System	26 Aug 2020 21:07:34
	System	26 Aug 2020 21:07:34

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-26T17:07:07', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '225219c6-91ea-4658-b4db-de9e239e9090'	System	26 Aug 2020 21:07:34
User entered 'No (N)'	System	26 Aug 2020 21:07:34

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-26T17:07:28', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '225219c6-91ea-4658-b4db-de9e239e9090' User entered '26 Aug 2020 17:07'	System	26 Aug 2020 21:07:34
	System	26 Aug 2020 21:07:34

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '26 Aug 2020 16:55'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '26 Aug 2020 19:25'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	26 Aug 2020 21:04:53
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-26T21:39:43', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'be75635d-c2da-4b66-a294-52d3977a8811' User entered 'Yes (Y)'	System	27 Aug 2020 01:40:10
	System	27 Aug 2020 01:40:10

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-26T21:39:55', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'be75635d-c2da-4b66-a294-52d3977a8811' User entered '96.9'	System	27 Aug 2020 01:40:10
	System	27 Aug 2020 01:40:10

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-26T21:39:59', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'be75635d-c2da-4b66-a294-52d3977a8811'	System	27 Aug 2020 01:40:10
User entered 'No (N)'	System	27 Aug 2020 01:40:10

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-26T21:40:07', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'be75635d-c2da-4b66-a294-52d3977a8811'	System	27 Aug 2020 01:40:10
User entered '26 Aug 2020 21:40'	System	27 Aug 2020 01:40:10

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '26 Aug 2020 20:20'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	26 Aug 2020 21:04:53
User entered 'Day 2'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:22:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-27T20:41:05', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '65aecbe2-d4c3-4541-a97a-017492372743' User entered 'Yes (Y)'	System	28 Aug 2020 00:41:36
	System	28 Aug 2020 00:41:36

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:22:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-27T20:41:14', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '65aecbe2-d4c3-4541-a97a-017492372743' User entered '97.1'	System	28 Aug 2020 00:41:36
	System	28 Aug 2020 00:41:36

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-27T20:41:19', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '65aecbe2-d4c3-4541-a97a-017492372743'	System	28 Aug 2020 00:41:36
User entered 'No (N)'	System	28 Aug 2020 00:41:36

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:22:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-27T20:41:32', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '65aecbe2-d4c3-4541-a97a-017492372743' User entered '27 Aug 2020 20:41'	System	28 Aug 2020 00:41:36
	System	28 Aug 2020 00:41:36

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	26 Aug 2020 21:04:53
User entered 'Day 3'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:22:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-28T21:34:21', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '7f7bcfda-eeed-4985-bd11-85a0602bf2f9'	System	29 Aug 2020 01:34:45
User entered 'Yes (Y)'	System	29 Aug 2020 01:34:45

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:22:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-28T21:34:28', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '7f7bcfda-eeed-4985-bd11-85a0602bf2f9' User entered '97.2'	System	29 Aug 2020 01:34:45
	System	29 Aug 2020 01:34:45

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-28T21:34:33', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '7f7bcfda-eeed-4985-bd11-85a0602bf2f9'	System	29 Aug 2020 01:34:45
User entered 'No (N)'	System	29 Aug 2020 01:34:45

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:22:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-28T21:34:40', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '7f7bcfda-eeed-4985-bd11-85a0602bf2f9'	System	29 Aug 2020 01:34:45
User entered '28 Aug 2020 21:34'	System	29 Aug 2020 01:34:45

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	26 Aug 2020 21:04:53
User entered 'Day 4'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:22:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-29T23:58:11', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '078e7f64-00e6-4cfc-a66d-3ad92fe12d9a' User entered 'Yes (Y)'	System	30 Aug 2020 03:58:33
	System	30 Aug 2020 03:58:33

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:22:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-29T23:58:18', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '078e7f64-00e6-4cfc-a66d-3ad92fe12d9a' User entered '97.9'	System	30 Aug 2020 03:58:33
	System	30 Aug 2020 03:58:33

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-29T23:58:24', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '078e7f64-00e6-4cfc-a66d-3ad92fe12d9a'	System	30 Aug 2020 03:58:33
User entered 'No (N)'	System	30 Aug 2020 03:58:33

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:22:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-29T23:58:30', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '078e7f64-00e6-4cfc-a66d-3ad92fe12d9a'	System	30 Aug 2020 03:58:33
User entered '29 Aug 2020 23:58'	System	30 Aug 2020 03:58:33

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	26 Aug 2020 21:04:53
User entered 'Day 5'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:22:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-30T23:07:12', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '7dc3e2c8-a5ca-4bb3-9d47-ff094b1b0f71' User entered 'Yes (Y)'	System	31 Aug 2020 03:07:31
	System	31 Aug 2020 03:07:31

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:22:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-30T23:07:19', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '7dc3e2c8-a5ca-4bb3-9d47-ff094b1b0f71' User entered '96.8'	System	31 Aug 2020 03:07:31
	System	31 Aug 2020 03:07:31

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-30T23:07:22', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '7dc3e2c8-a5ca-4bb3-9d47-ff094b1b0f71'	System	31 Aug 2020 03:07:31
User entered 'No (N)'	System	31 Aug 2020 03:07:31

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:22:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-30T23:07:28', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '7dc3e2c8-a5ca-4bb3-9d47-ff094b1b0f71' User entered '30 Aug 2020 23:07'	System	31 Aug 2020 03:07:31
	System	31 Aug 2020 03:07:31

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	26 Aug 2020 21:04:53
User entered 'Day 6'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:22:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-31T23:12:50', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '28a9e9c1-2a94-4b8c-ac4b-6ef651c4a238'	System	01 Sep 2020 03:13:08
User entered 'Yes (Y)'	System	01 Sep 2020 03:13:08

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:22:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-31T23:12:57', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '28a9e9c1-2a94-4b8c-ac4b-6ef651c4a238' User entered '97.0'	System	01 Sep 2020 03:13:08
	System	01 Sep 2020 03:13:08

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-31T23:13:00', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '28a9e9c1-2a94-4b8c-ac4b-6ef651c4a238'	System	01 Sep 2020 03:13:08
User entered 'No (N)'	System	01 Sep 2020 03:13:08

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:22:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-31T23:13:07', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '28a9e9c1-2a94-4b8c-ac4b-6ef651c4a238'	System	01 Sep 2020 03:13:08
User entered '31 Aug 2020 23:13'	System	01 Sep 2020 03:13:08

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	26 Aug 2020 21:04:53
User entered 'Day 7'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:22:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-09-01T21:30:24', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'cc9eb25f-fbf4-4c0a-bc56-2be2e8f73e20'	System	02 Sep 2020 01:30:47
User entered 'Yes (Y)'	System	02 Sep 2020 01:30:47

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:22:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-09-01T21:30:34', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'cc9eb25f-fbf4-4c0a-bc56-2be2e8f73e20' User entered '97.5'	System	02 Sep 2020 01:30:47
	System	02 Sep 2020 01:30:47

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-09-01T21:30:38', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'cc9eb25f-fbf4-4c0a-bc56-2be2e8f73e20'	System	02 Sep 2020 01:30:47
User entered 'No (N)'	System	02 Sep 2020 01:30:47

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:22:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-09-01T21:30:43', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'cc9eb25f-fbf4-4c0a-bc56-2be2e8f73e20'	System	02 Sep 2020 01:30:47
User entered '01 Sep 2020 21:30'	System	02 Sep 2020 01:30:47

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	26 Aug 2020 21:04:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-26T17:08:37', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '3fc49646-a4a5-4d2c-a46b-ee3841688e33'	System	26 Aug 2020 21:09:41
User entered 'None (1)'	System	26 Aug 2020 21:09:41

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-26T17:09:13', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '3fc49646-a4a5-4d2c-a46b-ee3841688e33' User entered 'No (N)'	System	26 Aug 2020 21:09:41
	System	26 Aug 2020 21:09:41

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-26T17:09:27', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '3fc49646-a4a5-4d2c-a46b-ee3841688e33' User entered 'No (N)'	System	26 Aug 2020 21:09:41
	System	26 Aug 2020 21:09:41

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-26T17:09:33', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '3fc49646-a4a5-4d2c-a46b-ee3841688e33'	System	26 Aug 2020 21:09:41
User entered 'None (1)'	System	26 Aug 2020 21:09:41

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-26T17:09:38', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '3fc49646-a4a5-4d2c-a46b-ee3841688e33' User entered '26 Aug 2020 17:09'	System	26 Aug 2020 21:09:41
	System	26 Aug 2020 21:09:41

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '26 Aug 2020 16:55'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '26 Aug 2020 19:25'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	26 Aug 2020 21:04:53
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-26T21:40:21', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'b43af646-a4b9-4956-802c-1e9e9cde6c79'	System	27 Aug 2020 01:40:47
User entered 'None (1)'	System	27 Aug 2020 01:40:47

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-26T21:40:25', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'b43af646-a4b9-4956-802c-1e9e9cde6c79'	System	27 Aug 2020 01:40:47
User entered 'No (N)'	System	27 Aug 2020 01:40:47

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-26T21:40:31', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'b43af646-a4b9-4956-802c-1e9e9cde6c79'	System	27 Aug 2020 01:40:47
User entered 'No (N)'	System	27 Aug 2020 01:40:47

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-26T21:40:36', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'b43af646-a4b9-4956-802c-1e9e9cde6c79'	System	27 Aug 2020 01:40:47
User entered 'None (1)'	System	27 Aug 2020 01:40:47

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-26T21:40:46', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'b43af646-a4b9-4956-802c-1e9e9cde6c79'	System	27 Aug 2020 01:40:47
User entered '26 Aug 2020 21:40'	System	27 Aug 2020 01:40:47

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '26 Aug 2020 20:20'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	26 Aug 2020 21:04:53
User entered 'Day 2'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:22:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-27T20:42:35', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'd084d702-a712-425c-8b2a-0d6d1ac7f4a7'	System	28 Aug 2020 00:42:57
User entered 'None (1)'	System	28 Aug 2020 00:42:57

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:22:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-27T20:42:39', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'd084d702-a712-425c-8b2a-0d6d1ac7f4a7'	System	28 Aug 2020 00:42:57
User entered 'No (N)'	System	28 Aug 2020 00:42:57

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-27T20:42:43', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'd084d702-a712-425c-8b2a-0d6d1ac7f4a7'	System	28 Aug 2020 00:42:57
User entered 'No (N)'	System	28 Aug 2020 00:42:57

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:22:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-27T20:42:47', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'd084d702-a712-425c-8b2a-0d6d1ac7f4a7'	System	28 Aug 2020 00:42:57
User entered 'None (1)'	System	28 Aug 2020 00:42:57

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:22:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-27T20:42:56', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'd084d702-a712-425c-8b2a-0d6d1ac7f4a7'	System	28 Aug 2020 00:42:57
User entered '27 Aug 2020 20:42'	System	28 Aug 2020 00:42:57

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	26 Aug 2020 21:04:53
User entered 'Day 3'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:22:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-28T21:35:19', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '3c956133-8893-4f79-92e1-739700e70827'	System	29 Aug 2020 01:35:53
User entered 'None (1)'	System	29 Aug 2020 01:35:53

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:22:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-28T21:35:23', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '3c956133-8893-4f79-92e1-739700e70827'	System	29 Aug 2020 01:35:53
User entered 'No (N)'	System	29 Aug 2020 01:35:53

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-28T21:35:27', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '3c956133-8893-4f79-92e1-739700e70827'	System	29 Aug 2020 01:35:53
User entered 'No (N)'	System	29 Aug 2020 01:35:53

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:22:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-28T21:35:40', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '3c956133-8893-4f79-92e1-739700e70827'	System	29 Aug 2020 01:35:53
User entered 'None (1)'	System	29 Aug 2020 01:35:53

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:22:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-28T21:35:51', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '3c956133-8893-4f79-92e1-739700e70827'	System	29 Aug 2020 01:35:53
User entered '28 Aug 2020 21:35'	System	29 Aug 2020 01:35:53

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	26 Aug 2020 21:04:53
User entered 'Day 4'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:22:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-29T23:58:53', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'a545cfd-f-e17f-4f7d-bf78-3cc2d252b5ed' User entered 'None (1)'	System	30 Aug 2020 03:59:22
	System	30 Aug 2020 03:59:22

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:22:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-29T23:58:56', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'a545cfd-f-e17f-4f7d-bf78-3cc2d252b5ed'	System	30 Aug 2020 03:59:22
User entered 'No (N)'	System	30 Aug 2020 03:59:22

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-29T23:59:00', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'a545cfd-f-e17f-4f7d-bf78-3cc2d252b5ed' User entered 'No (N)'	System	30 Aug 2020 03:59:22
	System	30 Aug 2020 03:59:22

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:22:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-29T23:59:10', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'a545cfd-f-e17f-4f7d-bf78-3cc2d252b5ed' User entered 'None (1)'	System	30 Aug 2020 03:59:22
	System	30 Aug 2020 03:59:22

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:22:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-29T23:59:19', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'a545cfd-f-e17f-4f7d-bf78-3cc2d252b5ed' User entered '29 Aug 2020 23:59'	System	30 Aug 2020 03:59:22
	System	30 Aug 2020 03:59:22

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	26 Aug 2020 21:04:53
User entered 'Day 5'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:22:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-30T23:07:34', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'd9be0433-13af-43a2-9e71-96c5cdc02115'	System	31 Aug 2020 03:08:11
User entered 'None (1)'	System	31 Aug 2020 03:08:11

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:22:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-30T23:07:38', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'd9be0433-13af-43a2-9e71-96c5cdc02115'	System	31 Aug 2020 03:08:11
User entered 'No (N)'	System	31 Aug 2020 03:08:11

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-30T23:07:46', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'd9be0433-13af-43a2-9e71-96c5cdc02115'	System	31 Aug 2020 03:08:11
User entered 'No (N)'	System	31 Aug 2020 03:08:11

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:22:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-30T23:08:01', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'd9be0433-13af-43a2-9e71-96c5cdc02115'	System	31 Aug 2020 03:08:11
User entered 'None (1)'	System	31 Aug 2020 03:08:11

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:22:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-30T23:08:07', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'd9be0433-13af-43a2-9e71-96c5cdc02115'	System	31 Aug 2020 03:08:11
User entered '30 Aug 2020 23:08'	System	31 Aug 2020 03:08:11

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	26 Aug 2020 21:04:53
User entered 'Day 6'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:22:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-31T23:13:22', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '8384a811-ed0a-400e-912f-cc7b4a193652'	System	01 Sep 2020 03:14:06
User entered 'None (1)'	System	01 Sep 2020 03:14:06

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:22:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-31T23:13:26', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '8384a811-ed0a-400e-912f-cc7b4a193652'	System	01 Sep 2020 03:14:06
User entered 'No (N)'	System	01 Sep 2020 03:14:06

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-31T23:13:30', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '8384a811-ed0a-400e-912f-cc7b4a193652' User entered 'No (N)'	System	01 Sep 2020 03:14:06
	System	01 Sep 2020 03:14:06

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:22:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-31T23:13:46', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '8384a811-ed0a-400e-912f-cc7b4a193652'	System	01 Sep 2020 03:14:06
User entered 'None (1)'	System	01 Sep 2020 03:14:06

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:22:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-31T23:14:00', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '8384a811-ed0a-400e-912f-cc7b4a193652'	System	01 Sep 2020 03:14:06
User entered '31 Aug 2020 23:14'	System	01 Sep 2020 03:14:06

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	26 Aug 2020 21:04:53
User entered 'Day 7'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:22:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-09-01T21:30:56', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'bb1f61b8-e26e-4959-811b-cc63a317ca1e'	System	02 Sep 2020 01:31:42
User entered 'None (1)'	System	02 Sep 2020 01:31:42

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:22:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-09-01T21:31:01', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'bb1f61b8-e26e-4959-811b-cc63a317ca1e'	System	02 Sep 2020 01:31:42
User entered 'No (N)'	System	02 Sep 2020 01:31:42

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-09-01T21:31:16', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'bb1f61b8-e26e-4959-811b-cc63a317ca1e' User entered 'No (N)'	System	02 Sep 2020 01:31:42
	System	02 Sep 2020 01:31:42

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:22:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-09-01T21:31:34', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'bb1f61b8-e26e-4959-811b-cc63a317ca1e' User entered 'None (1)'	System	02 Sep 2020 01:31:42
	System	02 Sep 2020 01:31:42

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:22:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-09-01T21:31:40', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'bb1f61b8-e26e-4959-811b-cc63a317ca1e'	System	02 Sep 2020 01:31:42
User entered '01 Sep 2020 21:31'	System	02 Sep 2020 01:31:42

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	26 Aug 2020 21:04:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-26T17:09:48', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'e1197456-de2a-4dfb-ac21-3e97d6f4ddb'	System	26 Aug 2020 21:10:26
User entered 'None (0)'	System	26 Aug 2020 21:10:26

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-26T17:09:53', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'e1197456-de2a-4dfb-ac21-3e97d6f4ddb'	System	26 Aug 2020 21:10:26
User entered 'None (0)'	System	26 Aug 2020 21:10:26

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-26T17:09:56', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'e1197456-de2a-4dfb-ac21-3e97d6f4ddb'	System	26 Aug 2020 21:10:26
User entered 'None (0)'	System	26 Aug 2020 21:10:26

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-26T17:10:00', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'e1197456-de2a-4dfb-ac21-3e97d6f4ddb'	System	26 Aug 2020 21:10:26
User entered 'None (0)'	System	26 Aug 2020 21:10:26

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-26T17:10:03', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'e1197456-de2a-4dfb-ac21-3e97d6f4ddb'	System	26 Aug 2020 21:10:26
User entered 'None (0)'	System	26 Aug 2020 21:10:26

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-26T17:10:11', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'e1197456-de2a-4dfb-ac21-3e97d6f4ddb'	System	26 Aug 2020 21:10:26
User entered 'None (0)'	System	26 Aug 2020 21:10:26

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

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)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-26T17:10:19', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'e1197456-de2a-4dfb-ac21-3e97d6f4ddb'	System	26 Aug 2020 21:10:26
User entered 'No (N)'	System	26 Aug 2020 21:10:26

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-26T17:10:23', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'e1197456-de2a-4dfb-ac21-3e97d6f4ddb'	System	26 Aug 2020 21:10:26
User entered '26 Aug 2020 17:10'	System	26 Aug 2020 21:10:26

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '26 Aug 2020 16:55'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '26 Aug 2020 19:25'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	26 Aug 2020 21:04:53
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-26T21:41:09', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'f1e47524-2da1-4195-86d1-69636b81caf2'	System	27 Aug 2020 01:41:52
User entered 'None (0)'	System	27 Aug 2020 01:41:52

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-26T21:41:15', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'f1e47524-2da1-4195-86d1-69636b81caf2'	System	27 Aug 2020 01:41:52
User entered 'None (0)'	System	27 Aug 2020 01:41:52

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-26T21:41:19', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'f1e47524-2da1-4195-86d1-69636b81caf2' User entered 'None (0)'	System	27 Aug 2020 01:41:52
	System	27 Aug 2020 01:41:52

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-26T21:41:23', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'f1e47524-2da1-4195-86d1-69636b81caf2' User entered 'None (0)'	System	27 Aug 2020 01:41:52
	System	27 Aug 2020 01:41:52

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-26T21:41:26', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'f1e47524-2da1-4195-86d1-69636b81caf2' User entered 'None (0)'	System	27 Aug 2020 01:41:52
	System	27 Aug 2020 01:41:52

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-26T21:41:29', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'f1e47524-2da1-4195-86d1-69636b81caf2'	System	27 Aug 2020 01:41:52
User entered 'None (0)'	System	27 Aug 2020 01:41:52

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

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)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-26T21:41:35', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'f1e47524-2da1-4195-86d1-69636b81caf2'	System	27 Aug 2020 01:41:52
User entered 'No (N)'	System	27 Aug 2020 01:41:52

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-26T21:41:48', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'f1e47524-2da1-4195-86d1-69636b81caf2'	System	27 Aug 2020 01:41:52
User entered '26 Aug 2020 21:41'	System	27 Aug 2020 01:41:52

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '26 Aug 2020 20:20'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	26 Aug 2020 21:04:53
User entered 'Day 2'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:22:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-27T20:43:09', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '63b62cc2-1d35-458c-8089-690e85162b5e'	System	28 Aug 2020 00:45:56
User entered 'No interference with activity (1)'	System	28 Aug 2020 00:45:56

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:22:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-27T20:44:00', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '63b62cc2-1d35-458c-8089-690e85162b5e'	System	28 Aug 2020 00:45:56
User entered 'Some interference with activity (2)'	System	28 Aug 2020 00:45:56

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:22:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-27T20:43:56', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '63b62cc2-1d35-458c-8089-690e85162b5e' User entered 'None (0)'	System	28 Aug 2020 00:45:56
	System	28 Aug 2020 00:45:56

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:22:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-27T20:44:50', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '63b62cc2-1d35-458c-8089-690e85162b5e'	System	28 Aug 2020 00:45:56
User entered 'No interference with activity (1)'	System	28 Aug 2020 00:45:56

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:22:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-27T20:44:54', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '63b62cc2-1d35-458c-8089-690e85162b5e' User entered 'None (0)'	System	28 Aug 2020 00:45:56
	System	28 Aug 2020 00:45:56

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:22:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-27T20:45:10', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '63b62cc2-1d35-458c-8089-690e85162b5e'	System	28 Aug 2020 00:45:56
User entered 'Some interference with activity not requiring medical attention (2)'	System	28 Aug 2020 00:45:56

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:22:03

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)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-27T20:45:16', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '63b62cc2-1d35-458c-8089-690e85162b5e' User entered 'No (N)'	System	28 Aug 2020 00:45:56
	System	28 Aug 2020 00:45:56

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:22:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-27T20:45:52', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '63b62cc2-1d35-458c-8089-690e85162b5e' User entered '27 Aug 2020 20:45'	System	28 Aug 2020 00:45:56
	System	28 Aug 2020 00:45:56

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	26 Aug 2020 21:04:53
User entered 'Day 3'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:22:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-28T21:36:04', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '4845483a-a2f8-4105-851a-6ce56a56a8ea'	System	29 Aug 2020 01:37:15
User entered 'No interference with activity (1)'	System	29 Aug 2020 01:37:15

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:22:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-28T21:36:10', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '4845483a-a2f8-4105-851a-6ce56a56a8ea' User entered 'Some interference with activity (2)'	System	29 Aug 2020 01:37:15
	System	29 Aug 2020 01:37:15

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:22:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-28T21:36:18', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '4845483a-a2f8-4105-851a-6ce56a56a8ea' User entered 'None (0)'	System	29 Aug 2020 01:37:15
	System	29 Aug 2020 01:37:15

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:22:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-28T21:36:24', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '4845483a-a2f8-4105-851a-6ce56a56a8ea' User entered 'None (0)'	System	29 Aug 2020 01:37:15
	System	29 Aug 2020 01:37:15

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:22:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-28T21:36:27', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '4845483a-a2f8-4105-851a-6ce56a56a8ea' User entered 'None (0)'	System	29 Aug 2020 01:37:15
	System	29 Aug 2020 01:37:15

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:22:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-28T21:36:54', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '4845483a-a2f8-4105-851a-6ce56a56a8ea'	System	29 Aug 2020 01:37:15
User entered 'Some interference with activity not requiring medical attention (2)'	System	29 Aug 2020 01:37:15

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:22:03

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)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-28T21:37:02', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '4845483a-a2f8-4105-851a-6ce56a56a8ea' User entered 'No (N)'	System	29 Aug 2020 01:37:15
	System	29 Aug 2020 01:37:15

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:22:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-28T21:37:13', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '4845483a-a2f8-4105-851a-6ce56a56a8ea' User entered '28 Aug 2020 21:37'	System	29 Aug 2020 01:37:15
	System	29 Aug 2020 01:37:15

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	26 Aug 2020 21:04:53
User entered 'Day 4'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:22:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-29T23:59:26', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'c8be0c09-6fdf-4c50-901b-565edfcba4ca' User entered 'None (0)'	System	30 Aug 2020 04:00:20
	System	30 Aug 2020 04:00:20

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:22:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-29T23:59:36', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'c8be0c09-6fdf-4c50-901b-565edfcba4ca'	System	30 Aug 2020 04:00:20
User entered 'No interference with activity (1)'	System	30 Aug 2020 04:00:20

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:22:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-29T23:59:41', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'c8be0c09-6fdf-4c50-901b-565edfcba4ca' User entered 'None (0)'	System	30 Aug 2020 04:00:20
	System	30 Aug 2020 04:00:20

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:22:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-29T23:59:44', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'c8be0c09-6fdf-4c50-901b-565edfcba4ca' User entered 'None (0)'	System	30 Aug 2020 04:00:20
	System	30 Aug 2020 04:00:20

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:22:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-29T23:59:47', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'c8be0c09-6fdf-4c50-901b-565edfcba4ca' User entered 'None (0)'	System	30 Aug 2020 04:00:20
	System	30 Aug 2020 04:00:20

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:22:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-29T23:59:55', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'c8be0c09-6fdf-4c50-901b-565edfcba4ca' User entered 'No interference with activity (1)'	System	30 Aug 2020 04:00:20
	System	30 Aug 2020 04:00:20

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:22:03

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)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-30T00:00:00', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'c8be0c09-6fdf-4c50-901b-565edfcba4ca' User entered 'No (N)'	System	30 Aug 2020 04:00:20
	System	30 Aug 2020 04:00:20

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:22:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-30T00:00:17', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'c8be0c09-6fdf-4c50-901b-565edfcba4ca' User entered '30 Aug 2020 00:00'	System	30 Aug 2020 04:00:20
	System	30 Aug 2020 04:00:20

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	26 Aug 2020 21:04:53
User entered 'Day 5'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:22:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-30T23:08:16', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'b236c016-9c73-4687-9e49-0f608bc67c9c' User entered 'None (0)'	System	31 Aug 2020 03:09:12
	System	31 Aug 2020 03:09:12

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:22:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-30T23:08:38', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'b236c016-9c73-4687-9e49-0f608bc67c9c'	System	31 Aug 2020 03:09:12
User entered 'No interference with activity (1)'	System	31 Aug 2020 03:09:12

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:22:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-30T23:08:44', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'b236c016-9c73-4687-9e49-0f608bc67c9c' User entered 'None (0)'	System	31 Aug 2020 03:09:12
	System	31 Aug 2020 03:09:12

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:22:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-30T23:08:53', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'b236c016-9c73-4687-9e49-0f608bc67c9c'	System	31 Aug 2020 03:09:12
User entered 'No interference with activity (1)'	System	31 Aug 2020 03:09:12

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:22:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-30T23:08:56', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'b236c016-9c73-4687-9e49-0f608bc67c9c' User entered 'None (0)'	System	31 Aug 2020 03:09:12
	System	31 Aug 2020 03:09:12

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:22:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-30T23:09:00', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'b236c016-9c73-4687-9e49-0f608bc67c9c' User entered 'None (0)'	System	31 Aug 2020 03:09:12
	System	31 Aug 2020 03:09:12

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:22:03

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)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-30T23:09:06', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'b236c016-9c73-4687-9e49-0f608bc67c9c' User entered 'No (N)'	System	31 Aug 2020 03:09:12
	System	31 Aug 2020 03:09:12

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:22:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-30T23:09:09', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'b236c016-9c73-4687-9e49-0f608bc67c9c' User entered '30 Aug 2020 23:09'	System	31 Aug 2020 03:09:12
	System	31 Aug 2020 03:09:12

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	26 Aug 2020 21:04:53
User entered 'Day 6'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:22:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-31T23:14:08', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'beade9c9-ec04-4ed0-b664-840b4ad67b10' User entered 'None (0)'	System	01 Sep 2020 03:14:56
	System	01 Sep 2020 03:14:56

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:22:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-31T23:14:20', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'beade9c9-ec04-4ed0-b664-840b4ad67b10' User entered 'None (0)'	System	01 Sep 2020 03:14:56
	System	01 Sep 2020 03:14:56

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:22:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-31T23:14:26', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'beade9c9-ec04-4ed0-b664-840b4ad67b10' User entered 'None (0)'	System	01 Sep 2020 03:14:56
	System	01 Sep 2020 03:14:56

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:22:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-31T23:14:36', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'beade9c9-ec04-4ed0-b664-840b4ad67b10' User entered 'None (0)'	System	01 Sep 2020 03:14:56
	System	01 Sep 2020 03:14:56

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:22:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-31T23:14:39', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'beade9c9-ec04-4ed0-b664-840b4ad67b10' User entered 'None (0)'	System	01 Sep 2020 03:14:56
	System	01 Sep 2020 03:14:56

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:22:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-31T23:14:42', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'beade9c9-ec04-4ed0-b664-840b4ad67b10' User entered 'None (0)'	System	01 Sep 2020 03:14:56
	System	01 Sep 2020 03:14:56

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:22:03

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)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-31T23:14:49', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'beade9c9-ec04-4ed0-b664-840b4ad67b10' User entered 'No (N)'	System	01 Sep 2020 03:14:56
	System	01 Sep 2020 03:14:56

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:22:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-08-31T23:14:54', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'beade9c9-ec04-4ed0-b664-840b4ad67b10' User entered '31 Aug 2020 23:14'	System	01 Sep 2020 03:14:56
	System	01 Sep 2020 03:14:56

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	26 Aug 2020 21:04:53
User entered 'Day 7'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:22:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-09-01T21:33:03', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '81e192a3-d26a-42a2-bba5-989be820e69d'	System	02 Sep 2020 01:33:29
User entered 'No interference with activity (1)'	System	02 Sep 2020 01:33:29

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:22:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-09-01T21:33:00', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '81e192a3-d26a-42a2-bba5-989be820e69d' User entered 'None (0)'	System	02 Sep 2020 01:33:29
	System	02 Sep 2020 01:33:29

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:22:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-09-01T21:32:58', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '81e192a3-d26a-42a2-bba5-989be820e69d' User entered 'None (0)'	System	02 Sep 2020 01:33:29
	System	02 Sep 2020 01:33:29

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:22:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-09-01T21:32:56', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '81e192a3-d26a-42a2-bba5-989be820e69d' User entered 'None (0)'	System	02 Sep 2020 01:33:29
	System	02 Sep 2020 01:33:29

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:22:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-09-01T21:33:09', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '81e192a3-d26a-42a2-bba5-989be820e69d' User entered 'None (0)'	System	02 Sep 2020 01:33:29
	System	02 Sep 2020 01:33:29

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:22:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-09-01T21:33:13', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '81e192a3-d26a-42a2-bba5-989be820e69d' User entered 'None (0)'	System	02 Sep 2020 01:33:29
	System	02 Sep 2020 01:33:29

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:22:03

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)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-09-01T21:33:18', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '81e192a3-d26a-42a2-bba5-989be820e69d' User entered 'No (N)'	System	02 Sep 2020 01:33:29
	System	02 Sep 2020 01:33:29

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:22:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-09-01T21:33:27', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '81e192a3-d26a-42a2-bba5-989be820e69d' User entered '01 Sep 2020 21:33'	System	02 Sep 2020 01:33:29
	System	02 Sep 2020 01:33:29

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 21:04:53

US3122085

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	02 Sep 2020 01:33:29
User entered 'Day 8'	System	02 Sep 2020 01:33:29

US3122085

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:22:03

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-09-02T21:21:23', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '44795b42-c88d-4fad-bac6-64540d5ec0cd' User entered 'None (0)'	System	03 Sep 2020 01:21:36
	System	03 Sep 2020 01:21:36

US3122085

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:22:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-09-02T21:21:31', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '44795b42-c88d-4fad-bac6-64540d5ec0cd' User entered '02 Sep 2020 21:21'	System	03 Sep 2020 01:21:36
	System	03 Sep 2020 01:21:36

US3122085

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '02 Sep 2020 12:00'	System	02 Sep 2020 01:33:29

US3122085

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 01:33:29

US3122085

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	02 Sep 2020 01:33:29
User entered 'Day 8'	System	02 Sep 2020 01:33:29

US3122085

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:22:03

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)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-09-02T21:21:38', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '05a73068-156d-40b8-a9c9-b559671838be' User entered 'No (N)'	System	03 Sep 2020 01:21:45
	System	03 Sep 2020 01:21:45

US3122085

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:22:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-09-02T21:21:43', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '05a73068-156d-40b8-a9c9-b559671838be' User entered '02 Sep 2020 21:21'	System	03 Sep 2020 01:21:45
	System	03 Sep 2020 01:21:45

US3122085

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:22:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '02 Sep 2020 12:00'	System	02 Sep 2020 01:33:29

US3122085

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:22:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 01:33:29

US3122085

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	04 Sep 2020 14:19:18

US3122085

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '03 Sep 2020'	(b) (4) Leah Corts (b) (4)	04 Sep 2020 14:19:18

US3122085

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Leah Corts (b) (4)	04 Sep 2020 14:19:18

US3122085

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) Leah Corts (b) (4)	04 Sep 2020 14:19:18

US3122085

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	04 Sep 2020 14:23:55

US3122085

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User entered 'I'	System	04 Sep 2020 14:23:55

US3122085

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	16 Sep 2020 21:36:21

US3122085

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '10 Sep 2020'	(b) (4) Leah Corts (b) (4)	16 Sep 2020 21:36:21

US3122085

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Leah Corts (b) (4)	16 Sep 2020 21:36:21

US3122085

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) Leah Corts (b) (4)	16 Sep 2020 21:36:21

US3122085

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	16 Sep 2020 21:36:27

US3122085

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User entered 'I'	System	16 Sep 2020 21:36:27

US3122085

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	16 Sep 2020 21:37:24

US3122085

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '16 Sep 2020'	(b) (4) Leah Corts (b) (4)	16 Sep 2020 21:37:24

US3122085

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Leah Corts (b) (4)	16 Sep 2020 21:37:24

US3122085

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered empty.	(b) (4) Leah Corts (b) (4)	16 Sep 2020 21:37:24

US3122085

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	16 Sep 2020 21:37:30

US3122085

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User entered 'I'	System	16 Sep 2020 21:37:30

US3122085

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:22:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	28 Sep 2020 15:08:28

US3122085

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '25 Sep 2020'	(b) (4) Leah Corts (b) (4)	28 Sep 2020 15:08:28

US3122085

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:22:03

[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 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Clinic (Clinic)'	(b) (4) Leah Corts (b) (4)	28 Sep 2020 15:08:28

US3122085

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:22:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User entered 'VISIT3'	System	28 Sep 2020 15:08:28

US3122085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	28 Sep 2020 15:08:36

US3122085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered empty.	(b) (4) Leah Corts (b) (4)	28 Sep 2020 15:08:36

US3122085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered empty.	(b) (4) Leah Corts (b) (4)	28 Sep 2020 15:08:36

US3122085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User entered empty.	System	28 Sep 2020 15:08:36

US3122085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered empty.	(b) (4) Leah Corts (b) (4)	28 Sep 2020 15:08:36

US3122085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered empty.	(b) (4) Leah Corts (b) (4)	28 Sep 2020 15:08:36

US3122085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered empty.	(b) (4) Leah Corts (b) (4)	28 Sep 2020 15:08:36

US3122085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered empty.	(b) (4) Leah Corts (b) (4)	28 Sep 2020 15:08:36

US3122085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User entered empty.	System	28 Sep 2020 15:08:36

US3122085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered empty.	(b) (4) Leah Corts (b) (4)	28 Sep 2020 15:08:36

US3122085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User entered empty.	System	28 Sep 2020 15:08:36

US3122085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered empty.	(b) (4) Leah Corts (b) (4)	28 Sep 2020 15:08:36

US3122085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User entered empty.	System	28 Sep 2020 15:08:36

US3122085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered empty.	(b) (4) Leah Corts (b) (4)	28 Sep 2020 15:08:36

US3122085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User entered empty.	System	28 Sep 2020 15:08:36

US3122085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54

US3122085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54

US3122085

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:22:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	28 Sep 2020 15:08:43

US3122085

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:22:03

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered empty.	(b) (4) Leah Corts (b) (4)	28 Sep 2020 15:08:43

US3122085

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:22:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	28 Sep 2020 15:08:59

US3122085

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:22:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '25 Sep 2020'	(b) (4) Leah Corts (b) (4)	28 Sep 2020 15:08:59

US3122085

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:22:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '15:20'	(b) (4) Leah Corts (b) (4)	28 Sep 2020 15:08:59

US3122085

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User entered '25 Sep 2020 15:20'	System	28 Sep 2020 15:08:59

US3122085

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	28 Sep 2020 15:09:04

US3122085

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User entered '1'	System	28 Sep 2020 15:09:04

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered 'Day 64'	System	29 Jul 2020 00:02:05

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-09-30T00:40:51', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '2d7ac5c5-ac6f-4c9e-ac68-2e13f502f1e3'	System	30 Sep 2020 04:41:10
User entered 'No (N)'	System	30 Sep 2020 04:41:10

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Have you been exposed to someone with 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)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-09-30T00:40:59', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '2d7ac5c5-ac6f-4c9e-ac68-2e13f502f1e3'	System	30 Sep 2020 04:41:10
User entered 'No (N)'	System	30 Sep 2020 04:41:10

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-09-30T00:41:07', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '2d7ac5c5-ac6f-4c9e-ac68-2e13f502f1e3' User entered '30 Sep 2020 00:41:07'	System	30 Sep 2020 04:41:10
	System	30 Sep 2020 04:41:10

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered '27 Sep 2020 00:01'	System	29 Jul 2020 00:02:05

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered '01 Oct 2020 23:59'	System	29 Jul 2020 00:02:05

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered 'Day 71'	System	29 Jul 2020 00:02:05

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-10-04T19:15:25', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '36db8e7e-a58d-4c66-8fba-5b484fc872c6' User entered 'No (N)'	System	04 Oct 2020 23:15:46
	System	04 Oct 2020 23:15:46

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Have you been exposed to someone with 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)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-10-04T19:15:37', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '36db8e7e-a58d-4c66-8fba-5b484fc872c6'	System	04 Oct 2020 23:15:46
User entered 'No (N)'	System	04 Oct 2020 23:15:46

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-10-04T19:15:42', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '36db8e7e-a58d-4c66-8fba-5b484fc872c6' User entered '04 Oct 2020 19:15:42'	System	04 Oct 2020 23:15:46
	System	04 Oct 2020 23:15:46

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered '04 Oct 2020 00:01'	System	29 Jul 2020 00:02:05

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered '08 Oct 2020 23:59'	System	29 Jul 2020 00:02:05

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered 'Day 78'	System	29 Jul 2020 00:02:05

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-10-11T15:29:57', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '11891cb4-175a-4680-ba3f-48863383436c' User entered 'No (N)'	System	19 Oct 2020 16:45:16
	System	19 Oct 2020 16:45:16

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Have you been exposed to someone with 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)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-10-11T15:30:10', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '11891cb4-175a-4680-ba3f-48863383436c'	System	19 Oct 2020 16:45:16
User entered 'No (N)'	System	19 Oct 2020 16:45:16

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-10-11T15:30:17', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '11891cb4-175a-4680-ba3f-48863383436c' User entered '11 Oct 2020 15:30:17'	System	19 Oct 2020 16:45:16
	System	19 Oct 2020 16:45:16

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered '11 Oct 2020 00:01'	System	29 Jul 2020 00:02:05

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered '15 Oct 2020 23:59'	System	29 Jul 2020 00:02:05

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered 'Day 92'	System	29 Jul 2020 00:02:05

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[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)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-10-26T13:57:02', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'fc12afad-7d0f-4ec2-b9e6-e712ed2abe53'	System	26 Oct 2020 17:57:15
User entered 'No (N)'	System	26 Oct 2020 17:57:15

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Have you been exposed to someone with 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)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-10-26T13:57:07', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'fc12afad-7d0f-4ec2-b9e6-e712ed2abe53'	System	26 Oct 2020 17:57:15
User entered 'No (N)'	System	26 Oct 2020 17:57:15

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-10-26T13:57:13', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'fc12afad-7d0f-4ec2-b9e6-e712ed2abe53' User entered '26 Oct 2020 13:57:13'	System	26 Oct 2020 17:57:15
	System	26 Oct 2020 17:57:15

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered '25 Oct 2020 00:01'	System	29 Jul 2020 00:02:05

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered '29 Oct 2020 23:59'	System	29 Jul 2020 00:02:05

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered 'Day 99'	System	29 Jul 2020 00:02:05

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[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)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-11-02T16:39:04', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '3e6fa22f-aa99-4746-ab46-60075833d3ca' User entered 'No (N)'	System	02 Nov 2020 21:39:17
	System	02 Nov 2020 21:39:17

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Have you been exposed to someone with 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)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-11-02T16:39:10', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '3e6fa22f-aa99-4746-ab46-60075833d3ca' User entered 'No (N)'	System	02 Nov 2020 21:39:17
	System	02 Nov 2020 21:39:17

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-11-02T16:39:14', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '3e6fa22f-aa99-4746-ab46-60075833d3ca' User entered '02 Nov 2020 16:39:14'	System	02 Nov 2020 21:39:17
	System	02 Nov 2020 21:39:17

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered '01 Nov 2020 00:01'	System	29 Jul 2020 00:02:05

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered '05 Nov 2020 23:59'	System	29 Jul 2020 00:02:05

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered 'Day 106'	System	29 Jul 2020 00:02:05

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[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)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-11-10T10:02:29', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'cae2e382-f08f-4df2-bde3-4fa8eac9ae56'	System	17 Nov 2020 22:45:34
User entered 'No (N)'	System	17 Nov 2020 22:45:34

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Have you been exposed to someone with 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)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-11-10T10:02:50', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'cae2e382-f08f-4df2-bde3-4fa8eac9ae56'	System	17 Nov 2020 22:45:34
User entered 'No (N)'	System	17 Nov 2020 22:45:34

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-11-10T10:03:01', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'cae2e382-f08f-4df2-bde3-4fa8eac9ae56'	System	17 Nov 2020 22:45:34
User entered '10 Nov 2020 10:03:01'	System	17 Nov 2020 22:45:34

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered '08 Nov 2020 00:01'	System	29 Jul 2020 00:02:05

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered '12 Nov 2020 23:59'	System	29 Jul 2020 00:02:05

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered 'Day 113'	System	29 Jul 2020 00:02:05

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-11-17T17:45:42', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'd978294f-4c70-452f-b0a3-3bb818af7994'	System	17 Nov 2020 22:48:08
User entered 'Yes (Y)'	System	17 Nov 2020 22:48:08

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Have you been exposed to someone with 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)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-11-17T17:45:55', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'd978294f-4c70-452f-b0a3-3bb818af7994'	System	17 Nov 2020 22:48:08
User entered 'No (N)'	System	17 Nov 2020 22:48:08

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-11-17T17:46:15', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'd978294f-4c70-452f-b0a3-3bb818af7994'	System	17 Nov 2020 22:48:08
User entered 'Yes (Y)'	System	17 Nov 2020 22:48:08

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-11-17T17:47:04', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'd978294f-4c70-452f-b0a3-3bb818af7994' User entered '0'	System	17 Nov 2020 22:48:08
	System	17 Nov 2020 22:48:08

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-11-17T17:47:04', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'd978294f-4c70-452f-b0a3-3bb818af7994'	System	17 Nov 2020 22:48:08
User entered '1'	System	17 Nov 2020 22:48:08

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-11-17T17:47:04', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'd978294f-4c70-452f-b0a3-3bb818af7994'	System	17 Nov 2020 22:48:08
User entered '1'	System	17 Nov 2020 22:48:08

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-11-17T17:47:04', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'd978294f-4c70-452f-b0a3-3bb818af7994' User entered '0'	System	17 Nov 2020 22:48:08
	System	17 Nov 2020 22:48:08

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-11-17T17:47:04', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'd978294f-4c70-452f-b0a3-3bb818af7994'	System	17 Nov 2020 22:48:08
User entered '0'	System	17 Nov 2020 22:48:08

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-11-17T17:47:04', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'd978294f-4c70-452f-b0a3-3bb818af7994'	System	17 Nov 2020 22:48:08
User entered '1'	System	17 Nov 2020 22:48:08

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-11-17T17:47:04', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'd978294f-4c70-452f-b0a3-3bb818af7994' User entered '0'	System	17 Nov 2020 22:48:08
	System	17 Nov 2020 22:48:08

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-11-17T17:47:04', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'd978294f-4c70-452f-b0a3-3bb818af7994' User entered '0'	System	17 Nov 2020 22:48:08
	System	17 Nov 2020 22:48:08

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-11-17T17:47:04', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'd978294f-4c70-452f-b0a3-3bb818af7994' User entered '0'	System	17 Nov 2020 22:48:08
	System	17 Nov 2020 22:48:08

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-11-17T17:47:04', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'd978294f-4c70-452f-b0a3-3bb818af7994' User entered '0'	System	17 Nov 2020 22:48:08
	System	17 Nov 2020 22:48:08

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-11-17T17:47:04', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'd978294f-4c70-452f-b0a3-3bb818af7994' User entered '0'	System	17 Nov 2020 22:48:08
	System	17 Nov 2020 22:48:08

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-11-17T17:47:04', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'd978294f-4c70-452f-b0a3-3bb818af7994'	System	17 Nov 2020 22:48:08
User entered '1'	System	17 Nov 2020 22:48:08

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-11-17T17:47:04', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'd978294f-4c70-452f-b0a3-3bb818af7994' User entered '0'	System	17 Nov 2020 22:48:08
	System	17 Nov 2020 22:48:08

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-11-17T17:47:04', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'd978294f-4c70-452f-b0a3-3bb818af7994' User entered '1'	System	17 Nov 2020 22:48:08
	System	17 Nov 2020 22:48:08

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-11-17T17:47:04', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'd978294f-4c70-452f-b0a3-3bb818af7994' User entered '0'	System	17 Nov 2020 22:48:08
	System	17 Nov 2020 22:48:08

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-11-17T17:47:04', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'd978294f-4c70-452f-b0a3-3bb818af7994' User entered '0'	System	17 Nov 2020 22:48:08
	System	17 Nov 2020 22:48:08

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-11-17T17:47:04', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'd978294f-4c70-452f-b0a3-3bb818af7994'	System	17 Nov 2020 22:48:08
User entered '0'	System	17 Nov 2020 22:48:08

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-11-17T17:47:26', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'd978294f-4c70-452f-b0a3-3bb818af7994'	System	17 Nov 2020 22:48:08
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Nov 2020 22:48:08

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-11-17T17:47:34', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'd978294f-4c70-452f-b0a3-3bb818af7994'	System	17 Nov 2020 22:48:08
User entered 'No (N)'	System	17 Nov 2020 22:48:08

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-11-17T17:47:58', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'd978294f-4c70-452f-b0a3-3bb818af7994' User entered '17 Nov 2020 17:47:58'	System	17 Nov 2020 22:48:08
	System	17 Nov 2020 22:48:08

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered '15 Nov 2020 00:01'	System	29 Jul 2020 00:02:05

US3122085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:41
Data entry locked.	System	29 Jul 2020 00:02:05
User entered '19 Nov 2020 23:59'	System	29 Jul 2020 00:02:05

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-11-26T00:54:04', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '24ec891f-603a-4781-9b95-6583efb5135f' User entered 'Yes (Y)'	System	26 Nov 2020 05:56:05
	System	26 Nov 2020 05:56:05

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Have you been exposed to someone with 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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-11-26T00:54:12', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '24ec891f-603a-4781-9b95-6583efb5135f' User entered 'No (N)'	System	26 Nov 2020 05:56:05
	System	26 Nov 2020 05:56:05

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Have you experienced any new COVID-19 disease symptoms 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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-11-26T00:54:21', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '24ec891f-603a-4781-9b95-6583efb5135f' User entered 'No (N)'	System	26 Nov 2020 05:56:05
	System	26 Nov 2020 05:56:05

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Have you had to contact a healthcare provider 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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-11-26T00:55:55', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '24ec891f-603a-4781-9b95-6583efb5135f' User entered 'No (N)'	System	26 Nov 2020 05:56:05
	System	26 Nov 2020 05:56:05

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-11-26T00:56:02', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '24ec891f-603a-4781-9b95-6583efb5135f' User entered '26 Nov 2020 00:56:02'	System	26 Nov 2020 05:56:05
	System	26 Nov 2020 05:56:05

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-12-03T00:23:39', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '2d70732d-facd-4472-bae8-182d2a2734ae' User entered 'No (N)'	System	03 Dec 2020 05:24:02
	System	03 Dec 2020 05:24:02

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Have you been exposed to someone with 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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-12-03T00:23:48', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '2d70732d-facd-4472-bae8-182d2a2734ae' User entered 'No (N)'	System	03 Dec 2020 05:24:02
	System	03 Dec 2020 05:24:02

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-12-03T00:23:59', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '2d70732d-facd-4472-bae8-182d2a2734ae' User entered '03 Dec 2020 00:23:59'	System	03 Dec 2020 05:24:02
	System	03 Dec 2020 05:24:02

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-12-14T11:37:53', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '996caa14-8047-4abb-a2f5-a375db21d43e' User entered 'No (N)'	System	14 Dec 2020 16:38:07
	System	14 Dec 2020 16:38:07

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Have you been exposed to someone with 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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-12-14T11:37:58', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '996caa14-8047-4abb-a2f5-a375db21d43e' User entered 'No (N)'	System	14 Dec 2020 16:38:07
	System	14 Dec 2020 16:38:07

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-12-14T11:38:03', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '996caa14-8047-4abb-a2f5-a375db21d43e' User entered '14 Dec 2020 11:38:03'	System	14 Dec 2020 16:38:07
	System	14 Dec 2020 16:38:07

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-12-17T12:45:53', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '0c5f929a-d514-49c4-aa10-2c0041416ef5' User entered 'No (N)'	System	17 Dec 2020 17:46:17
	System	17 Dec 2020 17:46:17

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Have you been exposed to someone with 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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-12-17T12:45:57', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '0c5f929a-d514-49c4-aa10-2c0041416ef5' User entered 'No (N)'	System	17 Dec 2020 17:46:17
	System	17 Dec 2020 17:46:17

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-12-17T12:46:00', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '0c5f929a-d514-49c4-aa10-2c0041416ef5' User entered '17 Dec 2020 12:46:00'	System	17 Dec 2020 17:46:17
	System	17 Dec 2020 17:46:17

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-12-24T00:56:23', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'c821b788-6df8-4ff7-9474-cd701b27b904' User entered 'No (N)'	System	24 Dec 2020 05:56:45
	System	24 Dec 2020 05:56:45

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Have you been exposed to someone with 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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-12-24T00:56:36', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'c821b788-6df8-4ff7-9474-cd701b27b904' User entered 'No (N)'	System	24 Dec 2020 05:56:45
	System	24 Dec 2020 05:56:45

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-12-24T00:56:41', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'c821b788-6df8-4ff7-9474-cd701b27b904' User entered '24 Dec 2020 00:56:41'	System	24 Dec 2020 05:56:45
	System	24 Dec 2020 05:56:45

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-12-31T11:13:01', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '35e06288-c5af-477e-80a0-2fbffc0e4217' User entered 'No (N)'	System	31 Dec 2020 16:13:24
	System	31 Dec 2020 16:13:24

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Have you been exposed to someone with 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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-12-31T11:13:16', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '35e06288-c5af-477e-80a0-2fbffc0e4217' User entered 'No (N)'	System	31 Dec 2020 16:13:24
	System	31 Dec 2020 16:13:24

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2020-12-31T11:13:22', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '35e06288-c5af-477e-80a0-2fbffc0e4217' User entered '31 Dec 2020 11:13:22'	System	31 Dec 2020 16:13:24
	System	31 Dec 2020 16:13:24

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-01-07T14:55:20', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '8dd4dcc6-9b2f-4dd0-86fb-5c81942ed8a1' User entered 'No (N)'	System	07 Jan 2021 19:55:31
	System	07 Jan 2021 19:55:31

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Have you been exposed to someone with 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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-01-07T14:55:25', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '8dd4dcc6-9b2f-4dd0-86fb-5c81942ed8a1' User entered 'No (N)'	System	07 Jan 2021 19:55:31
	System	07 Jan 2021 19:55:31

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-01-07T14:55:29', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '8dd4dcc6-9b2f-4dd0-86fb-5c81942ed8a1' User entered '07 Jan 2021 14:55:29'	System	07 Jan 2021 19:55:31
	System	07 Jan 2021 19:55:31

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-01-14T15:54:12', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'a4578c88-690f-4fed-b534-0a68e0f893be' User entered 'Yes (Y)'	System	14 Jan 2021 20:55:15
	System	14 Jan 2021 20:55:15

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Have you been exposed to someone with 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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-01-14T15:54:19', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'a4578c88-690f-4fed-b534-0a68e0f893be' User entered 'No (N)'	System	14 Jan 2021 20:55:15
	System	14 Jan 2021 20:55:15

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Have you experienced any new COVID-19 disease symptoms 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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-01-14T15:54:27', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'a4578c88-690f-4fed-b534-0a68e0f893be' User entered 'No (N)'	System	14 Jan 2021 20:55:15
	System	14 Jan 2021 20:55:15

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Have you had to contact a healthcare provider 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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-01-14T15:54:36', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'a4578c88-690f-4fed-b534-0a68e0f893be' User entered 'Yes (Y)'	System	14 Jan 2021 20:55:15
	System	14 Jan 2021 20:55:15

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-01-14T15:54:54', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'a4578c88-690f-4fed-b534-0a68e0f893be'	System	14 Jan 2021 20:55:15
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Jan 2021 20:55:15

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-01-14T15:55:00', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'a4578c88-690f-4fed-b534-0a68e0f893be' User entered '14 Jan 2021 15:55:00'	System	14 Jan 2021 20:55:15
	System	14 Jan 2021 20:55:15

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-01-25T11:03:54', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'cb2a6413-0371-47d3-8ff4-639dc5488a2c' User entered 'No (N)'	System	25 Jan 2021 16:04:16
	System	25 Jan 2021 16:04:16

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Have you been exposed to someone with 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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-01-25T11:04:01', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'cb2a6413-0371-47d3-8ff4-639dc5488a2c' User entered 'No (N)'	System	25 Jan 2021 16:04:16
	System	25 Jan 2021 16:04:16

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-01-25T11:04:14', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'cb2a6413-0371-47d3-8ff4-639dc5488a2c' User entered '25 Jan 2021 11:04:14'	System	25 Jan 2021 16:04:16
	System	25 Jan 2021 16:04:16

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-01-28T10:37:39', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '7951e2b4-abba-4139-83ba-259e779dbc00' User entered 'No (N)'	System	28 Jan 2021 15:37:56
	System	28 Jan 2021 15:37:56

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Have you been exposed to someone with 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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-01-28T10:37:47', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '7951e2b4-abba-4139-83ba-259e779dbc00' User entered 'No (N)'	System	28 Jan 2021 15:37:56

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-01-28T10:37:54', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '7951e2b4-abba-4139-83ba-259e779dbc00' User entered '28 Jan 2021 10:37:54'	System	28 Jan 2021 15:37:56
	System	28 Jan 2021 15:37:56

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-02-04T10:55:45', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '22da8a65-101e-4e86-b144-1f0e5e85c7af' User entered 'No (N)'	System	04 Feb 2021 15:56:32
	System	04 Feb 2021 15:56:32

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Have you been exposed to someone with 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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-02-04T10:56:02', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '22da8a65-101e-4e86-b144-1f0e5e85c7af' User entered 'No (N)'	System	04 Feb 2021 15:56:32

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-02-04T10:56:28', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '22da8a65-101e-4e86-b144-1f0e5e85c7af' User entered '04 Feb 2021 10:56:28'	System	04 Feb 2021 15:56:32
	System	04 Feb 2021 15:56:32

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-02-11T12:51:10', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '61570e9c-1ed3-4018-a6c5-59ffe12b4324' User entered 'Yes (Y)'	System	11 Feb 2021 17:52:32
	System	11 Feb 2021 17:52:32

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Have you been exposed to someone with 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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-02-11T12:51:17', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '61570e9c-1ed3-4018-a6c5-59ffe12b4324' User entered 'No (N)'	System	11 Feb 2021 17:52:32
	System	11 Feb 2021 17:52:32

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Have you experienced any new COVID-19 disease symptoms 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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-02-11T12:51:37', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '61570e9c-1ed3-4018-a6c5-59ffe12b4324' User entered 'Yes (Y)'	System	11 Feb 2021 17:52:32
	System	11 Feb 2021 17:52:32

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-02-11T12:51:57', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '61570e9c-1ed3-4018-a6c5-59ffe12b4324' User entered '0'	System	11 Feb 2021 17:52:32
	System	11 Feb 2021 17:52:32

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-02-11T12:51:57', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '61570e9c-1ed3-4018-a6c5-59ffe12b4324'	System	11 Feb 2021 17:52:32
User entered '0'	System	11 Feb 2021 17:52:32

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-02-11T12:51:57', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '61570e9c-1ed3-4018-a6c5-59ffe12b4324'	System	11 Feb 2021 17:52:32
User entered '1'	System	11 Feb 2021 17:52:32

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-02-11T12:51:57', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '61570e9c-1ed3-4018-a6c5-59ffe12b4324' User entered '0'	System	11 Feb 2021 17:52:32

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-02-11T12:51:57', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '61570e9c-1ed3-4018-a6c5-59ffe12b4324'	System	11 Feb 2021 17:52:32
User entered '0'	System	11 Feb 2021 17:52:32

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-02-11T12:51:57', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '61570e9c-1ed3-4018-a6c5-59ffe12b4324'	System	11 Feb 2021 17:52:32
User entered '1'	System	11 Feb 2021 17:52:32

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-02-11T12:51:57', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '61570e9c-1ed3-4018-a6c5-59ffe12b4324' User entered '0'	System	11 Feb 2021 17:52:32

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-02-11T12:51:57', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '61570e9c-1ed3-4018-a6c5-59ffe12b4324' User entered '0'	System	11 Feb 2021 17:52:32
	System	11 Feb 2021 17:52:32

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-02-11T12:51:57', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '61570e9c-1ed3-4018-a6c5-59ffe12b4324' User entered '0'	System	11 Feb 2021 17:52:32
	System	11 Feb 2021 17:52:32

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-02-11T12:51:57', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '61570e9c-1ed3-4018-a6c5-59ffe12b4324' User entered '0'	System	11 Feb 2021 17:52:32

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-02-11T12:51:57', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '61570e9c-1ed3-4018-a6c5-59ffe12b4324' User entered '0'	System	11 Feb 2021 17:52:32
	System	11 Feb 2021 17:52:32

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-02-11T12:51:57', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '61570e9c-1ed3-4018-a6c5-59ffe12b4324'	System	11 Feb 2021 17:52:32
User entered '1'	System	11 Feb 2021 17:52:32

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-02-11T12:51:57', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '61570e9c-1ed3-4018-a6c5-59ffe12b4324' User entered '0'	System	11 Feb 2021 17:52:32
	System	11 Feb 2021 17:52:32

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-02-11T12:51:57', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '61570e9c-1ed3-4018-a6c5-59ffe12b4324' User entered '1'	System	11 Feb 2021 17:52:32
	System	11 Feb 2021 17:52:32

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-02-11T12:51:57', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '61570e9c-1ed3-4018-a6c5-59ffe12b4324' User entered '0'	System	11 Feb 2021 17:52:32

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-02-11T12:51:57', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '61570e9c-1ed3-4018-a6c5-59ffe12b4324' User entered '0'	System	11 Feb 2021 17:52:32
	System	11 Feb 2021 17:52:32

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-02-11T12:51:57', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '61570e9c-1ed3-4018-a6c5-59ffe12b4324' User entered '0'	System	11 Feb 2021 17:52:32

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-02-11T12:52:06', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '61570e9c-1ed3-4018-a6c5-59ffe12b4324'	System	11 Feb 2021 17:52:32
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Feb 2021 17:52:32

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Have you had to contact a healthcare provider 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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-02-11T12:52:15', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '61570e9c-1ed3-4018-a6c5-59ffe12b4324' User entered 'No (N)'	System	11 Feb 2021 17:52:32
	System	11 Feb 2021 17:52:32

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-02-11T12:52:22', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '61570e9c-1ed3-4018-a6c5-59ffe12b4324' User entered '11 Feb 2021 12:52:22'	System	11 Feb 2021 17:52:32
	System	11 Feb 2021 17:52:32

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-02-18T11:38:42', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'ca158aac-077f-48da-ab90-bea5a97d595a' User entered 'No (N)'	System	18 Feb 2021 16:38:57
	System	18 Feb 2021 16:38:57

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Have you been exposed to someone with 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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-02-18T11:38:37', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'ca158aac-077f-48da-ab90-bea5a97d595a' User entered 'No (N)'	System	18 Feb 2021 16:38:57
	System	18 Feb 2021 16:38:57

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-02-18T11:38:54', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'ca158aac-077f-48da-ab90-bea5a97d595a' User entered '18 Feb 2021 11:38:54'	System	18 Feb 2021 16:38:57
	System	18 Feb 2021 16:38:57

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-02-26T10:24:28', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '037278e9-0fb9-460c-b287-70ce57cb3dc8' User entered 'No (N)'	System	26 Feb 2021 15:24:42
	System	26 Feb 2021 15:24:42

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Have you been exposed to someone with 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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-02-26T10:22:48', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '037278e9-0fb9-460c-b287-70ce57cb3dc8' User entered 'No (N)'	System	26 Feb 2021 15:24:42
	System	26 Feb 2021 15:24:42

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-02-26T10:24:37', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '037278e9-0fb9-460c-b287-70ce57cb3dc8' User entered '26 Feb 2021 10:24:37'	System	26 Feb 2021 15:24:42
	System	26 Feb 2021 15:24:42

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-03-04T00:25:16', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'aa148643-6e45-48e5-8d30-a6b942875f06' User entered 'No (N)'	System	04 Mar 2021 05:25:31
	System	04 Mar 2021 05:25:31

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Have you been exposed to someone with 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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-03-04T00:25:19', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'aa148643-6e45-48e5-8d30-a6b942875f06' User entered 'No (N)'	System	04 Mar 2021 05:25:31
	System	04 Mar 2021 05:25:31

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-03-04T00:25:27', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'aa148643-6e45-48e5-8d30-a6b942875f06' User entered '04 Mar 2021 00:25:27'	System	04 Mar 2021 05:25:31
	System	04 Mar 2021 05:25:31

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-03-11T18:39:35', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '51dfec21-e4d1-42e1-9617-843a3772fa7f'	System	11 Mar 2021 23:39:55
User entered 'No (N)'	System	11 Mar 2021 23:39:55

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Have you been exposed to someone with 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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-03-11T18:39:40', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '51dfec21-e4d1-42e1-9617-843a3772fa7f'	System	11 Mar 2021 23:39:55
User entered 'No (N)'	System	11 Mar 2021 23:39:55

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-03-11T18:39:45', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '51dfec21-e4d1-42e1-9617-843a3772fa7f' User entered '11 Mar 2021 18:39:45'	System	11 Mar 2021 23:39:55
	System	11 Mar 2021 23:39:55

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-03-18T15:49:49', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '3b30a32e-bebb-4f53-be95-68a43e345242'	System	18 Mar 2021 19:50:32
User entered 'No (N)'	System	18 Mar 2021 19:50:32

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Have you been exposed to someone with 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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-03-18T15:50:10', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '3b30a32e-bebb-4f53-be95-68a43e345242' User entered 'No (N)'	System	18 Mar 2021 19:50:32
	System	18 Mar 2021 19:50:32

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-03-18T15:50:26', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '3b30a32e-bebb-4f53-be95-68a43e345242' User entered '18 Mar 2021 15:50:26'	System	18 Mar 2021 19:50:32
	System	18 Mar 2021 19:50:32

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-03-26T19:26:45', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'bca8bf94-6c42-46ea-afd1-d2bce119b8c8'	System	26 Mar 2021 23:28:05
User entered 'Yes (Y)'	System	26 Mar 2021 23:28:05

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Have you been exposed to someone with 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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-03-26T19:26:52', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'bca8bf94-6c42-46ea-afd1-d2bce119b8c8'	System	26 Mar 2021 23:28:05
User entered 'No (N)'	System	26 Mar 2021 23:28:05

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Have you experienced any new COVID-19 disease symptoms 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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-03-26T19:26:59', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'bca8bf94-6c42-46ea-afd1-d2bce119b8c8'	System	26 Mar 2021 23:28:05
User entered 'No (N)'	System	26 Mar 2021 23:28:05

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Have you had to contact a healthcare provider 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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-03-26T19:27:33', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'bca8bf94-6c42-46ea-afd1-d2bce119b8c8'	System	26 Mar 2021 23:28:05
User entered 'No (N)'	System	26 Mar 2021 23:28:05

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-03-26T19:28:02', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'bca8bf94-6c42-46ea-afd1-d2bce119b8c8' User entered '26 Mar 2021 19:28:02'	System	26 Mar 2021 23:28:05
	System	26 Mar 2021 23:28:05

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-04-01T13:10:48', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'd82401d7-6a1a-4211-afe1-5f91ba45dd13' User entered 'No (N)'	System	01 Apr 2021 17:11:04
	System	01 Apr 2021 17:11:04

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Have you been exposed to someone with 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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-04-01T13:10:57', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'd82401d7-6a1a-4211-afe1-5f91ba45dd13'	System	01 Apr 2021 17:11:04
User entered 'No (N)'	System	01 Apr 2021 17:11:04

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-04-01T13:11:01', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'd82401d7-6a1a-4211-afe1-5f91ba45dd13'	System	01 Apr 2021 17:11:04
User entered '01 Apr 2021 13:11:01'	System	01 Apr 2021 17:11:04

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-04-08T12:52:37', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'e9cdcbe9-f3ad-4f2b-8dc3-03e56ff52198'	System	08 Apr 2021 16:52:50
User entered 'No (N)'	System	08 Apr 2021 16:52:50

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Have you been exposed to someone with 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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-04-08T12:52:42', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'e9cdcbe9-f3ad-4f2b-8dc3-03e56ff52198'	System	08 Apr 2021 16:52:50
User entered 'No (N)'	System	08 Apr 2021 16:52:50

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-04-08T12:52:46', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'e9cdcbe9-f3ad-4f2b-8dc3-03e56ff52198'	System	08 Apr 2021 16:52:50
User entered '08 Apr 2021 12:52:46'	System	08 Apr 2021 16:52:50

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-04-15T01:38:03', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '4f3fd340-50e1-4244-bcf7-52d69ea252e6' User entered 'No (N)'	System	15 Apr 2021 05:38:18
	System	15 Apr 2021 05:38:18

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Have you been exposed to someone with 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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-04-15T01:38:10', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '4f3fd340-50e1-4244-bcf7-52d69ea252e6' User entered 'No (N)'	System	15 Apr 2021 05:38:18
	System	15 Apr 2021 05:38:18

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-04-15T01:38:15', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '4f3fd340-50e1-4244-bcf7-52d69ea252e6'	System	15 Apr 2021 05:38:18
User entered '15 Apr 2021 01:38:15'	System	15 Apr 2021 05:38:18

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-04-24T01:24:54', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'f629ac59-835a-489b-a39a-dd7353d81b57' User entered 'No (N)'	System	24 Apr 2021 05:25:06
	System	24 Apr 2021 05:25:06

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Have you been exposed to someone with 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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-04-24T01:24:58', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'f629ac59-835a-489b-a39a-dd7353d81b57' User entered 'No (N)'	System	24 Apr 2021 05:25:06
	System	24 Apr 2021 05:25:06

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-04-24T01:25:01', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'f629ac59-835a-489b-a39a-dd7353d81b57'	System	24 Apr 2021 05:25:06
User entered '24 Apr 2021 01:25:01'	System	24 Apr 2021 05:25:06

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-04-29T12:52:18', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'd93c55ef-ff30-4636-9783-48eb5bfc3fd4'	System	29 Apr 2021 16:52:37
User entered 'No (N)'	System	29 Apr 2021 16:52:37

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

Have you been exposed to someone with 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 (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-04-29T12:52:25', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'd93c55ef-ff30-4636-9783-48eb5bfc3fd4' User entered 'No (N)'	System	29 Apr 2021 16:52:37

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-04-29T12:52:31', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: 'd93c55ef-ff30-4636-9783-48eb5bfc3fd4'	System	29 Apr 2021 16:52:37
User entered '29 Apr 2021 12:52:31'	System	29 Apr 2021 16:52:37

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 02:31:54

US3122085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:22:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:31:54
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 02:31:54

US3122085

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:22:03

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)	30 Apr 2021 11:47:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-02-28T11:01:14', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '7e4f719a-ac22-4791-b748-99760c3045c5'	System	28 Feb 2021 16:01:28
User entered 'No (N)'	System	28 Feb 2021 16:01:28

US3122085

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:22:03

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (686B8EC4-7A8B-4FA9-976C-DC3F8EA84F39)', Time: '2021-02-28T11:01:26', User OID: 'PatientReportedOutcome (US3122085)', ODM File OID: '7e4f719a-ac22-4791-b748-99760c3045c5' User entered '28 Feb 2021 11:01:26'	System	28 Feb 2021 16:01:28
	System	28 Feb 2021 16:01:28

US3122085

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:17:41

US3122085

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '21 Oct 2020'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:17:41

US3122085

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:17:41

US3122085

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:17:41

US3122085

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:17:30

US3122085

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:54
User entered 'I'	System	22 Oct 2020 18:17:30

US3122085

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 23:36:06

US3122085

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User closed query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	(b) (4) System	17 Dec 2020 17:58:09
Query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered by data change (Site from System).	System	17 Dec 2020 17:58:09
User entered '17 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 17:58:09
User opened query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	09 Dec 2020 23:36:06
User entered '9 Dec 2020'	(b) (4), (b) (6)	09 Dec 2020 23:36:06

US3122085

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 23:36:06

US3122085

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 23:36:06

US3122085

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 23:36:12

US3122085

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User entered 'I'	System	09 Dec 2020 23:36:12

US3122085

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Dec 2020 19:41:11

US3122085

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	(b) (4), (b) (6)	04 Jan 2021 19:40:49
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'Contact out of window due to holiday' (Site from System).		04 Jan 2021 16:50:47
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	31 Dec 2020 19:41:11
User entered '31 Dec 2020'	(b) (4), (b) (6)	31 Dec 2020 19:41:11

US3122085

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	31 Dec 2020 19:41:11

US3122085

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Dec 2020 19:41:11

US3122085

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Dec 2020 19:41:26

US3122085

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User entered 'I'	System	31 Dec 2020 19:41:26

US3122085

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:41:11

US3122085

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:41:11

US3122085

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:41:11

US3122085

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:41:11

US3122085

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:41:15

US3122085

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User entered 'I'	System	21 Jan 2021 19:41:15

US3122085

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:22:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User closed query 'Per CDM: Visit 4 Day 209 and Visit OL-D29 are both dated 15FEB2021, however, Were vital signs assessed?' is not completed at this visit but at OL-D29 'Were vital signs assessed?' is YES and data is present. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor. Please review and update as appropriate.' (Site from DM).		31 Mar 2021 20:18:08
Query 'Per CDM: Visit 4 Day 209 and Visit OL-D29 are both dated 15FEB2021, however, Were vital signs assessed?' is not completed at this visit but at OL-D29 'Were vital signs assessed?' is YES and data is present. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor. Please review and update as appropriate. answered with 'updated' (Site from DM).		30 Mar 2021 13:26:38
User opened query 'Per CDM: Visit 4 Day 209 and Visit OL-D29 are both dated 15FEB2021, however, Were vital signs assessed?' is not completed at this visit but at OL-D29 'Were vital signs assessed?' is YES and data is present. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor. Please review and update as appropriate.' (Site from DM).		30 Mar 2021 06:23:45
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 15:08:15

US3122085

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 15:08:15

US3122085

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 15:08:15

US3122085

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:22:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User entered 'VISIT4'	System	12 Mar 2021 15:08:15

US3122085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User signature succeeded.	Matthew Hong (b) (4)	30 Mar 2021 13:55:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:26:13

US3122085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User signature succeeded.	Matthew Hong (b) (4)	30 Mar 2021 13:55:01
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:26:13

US3122085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User signature succeeded.	Matthew Hong (b) (4)	30 Mar 2021 13:55:01
User entered '10:11'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:26:13

US3122085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User entered '15 Feb 2021 10:11'	System	30 Mar 2021 13:26:13

US3122085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User signature succeeded.	Matthew Hong (b) (4)	30 Mar 2021 13:55:01
User entered '36.4' C	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:26:13

US3122085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User signature succeeded.	Matthew Hong (b) (4)	30 Mar 2021 13:55:01
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:26:13

US3122085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User signature succeeded.	Matthew Hong (b) (4)	30 Mar 2021 13:55:01
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:26:13

US3122085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User signature succeeded.	Matthew Hong (b) (4)	30 Mar 2021 13:55:01
User closed query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	30 Mar 2021 13:26:25
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	30 Mar 2021 13:26:25
User entered '61' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 13:26:25
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	30 Mar 2021 13:26:13
User entered '31'	(b) (4), (b) (6)	30 Mar 2021 13:26:13

US3122085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User entered 'bpm'	System	30 Mar 2021 13:26:13

US3122085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User signature succeeded.	Matthew Hong (b) (4)	30 Mar 2021 13:55:01
User entered '16'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:26:13

US3122085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User entered 'breaths/min'	System	30 Mar 2021 13:26:13

US3122085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User signature succeeded.	Matthew Hong (b) (4)	30 Mar 2021 13:55:01
User entered '125'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:26:13

US3122085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User entered 'mmHg'	System	30 Mar 2021 13:26:13

US3122085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User signature succeeded.	Matthew Hong (b) (4)	30 Mar 2021 13:55:01
User entered '87'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:26:13

US3122085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User entered 'mmHg'	System	30 Mar 2021 13:26:13

US3122085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28

US3122085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28

US3122085

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:22:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 15:08:33

US3122085

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:22:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 15:08:33

US3122085

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:22:03

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:57:21
User closed query 'Per Clinical: Site needs to add sample info' (Site from DM).		01 May 2021 05:51:34
User signature succeeded.	Matthew Hong (b) (4)	29 Apr 2021 21:02:57
Query 'Per Clinical: Site needs to add sample info' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 18:51:08
User closed query 'Was the sample collected? is No, however Date and/or Time is present. Please correct.' (Site from System).	System	29 Apr 2021 18:49:30
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 18:49:30
User entered 'Yes (Y)' reason for change: Data Entry Error		29 Apr 2021 18:49:30
User opened query 'Was the sample collected? is No, however Date and/or Time is present. Please correct.' (Site from System).	System	29 Apr 2021 18:49:25
User opened query 'Per Clinical: Site needs to add sample info' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 10:25:08
Data hard unlocked.		29 Apr 2021 10:25:02
Data hard locked.		14 Apr 2021 06:13:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered 'No (N)'	(b) (4), (b) (6)	12 Mar 2021 15:08:49

US3122085

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:22:03

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:57:21
User signature succeeded.	Matthew Hong (b) (4)	29 Apr 2021 21:02:57
Signature has been broken.	(b) (4)	29 Apr 2021 18:49:25
User entered '15 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 18:49:25
Data hard unlocked.		29 Apr 2021 10:25:02
Data hard locked.		14 Apr 2021 06:13:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 15:08:49

US3122085

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:22:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:57:21
User signature succeeded.	Matthew Hong (b) (4)	29 Apr 2021 21:02:57
Signature has been broken.	(b) (4)	29 Apr 2021 18:49:25
User entered '10:30' reason for change: Data Entry	(b) (4), (b) (6)	29 Apr 2021 18:49:25
Error		
Data hard unlocked.		29 Apr 2021 10:25:02
Data hard locked.		14 Apr 2021 06:13:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 15:08:49

US3122085

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:22:03

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:57:21
User entered '15 Feb 2021 10:30'	System	29 Apr 2021 18:49:25
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:25:02
Data hard locked.		14 Apr 2021 06:13:28
User entered empty.	System	12 Mar 2021 15:08:49

US3122085

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 15:08:53

US3122085

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:28
User entered 'I'	System	12 Mar 2021 15:08:53

US3122085

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:54:43
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 20:45:56

US3122085

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:54:43
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 20:45:56

US3122085

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:54:43
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 20:45:56

US3122085

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:54:43
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 20:45:56

US3122085

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:54:43
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 20:46:03

US3122085

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:54:43
User entered 'I'	System	23 Mar 2021 20:46:03

US3122085

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 20:03:21

US3122085

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
User entered '20 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 20:03:21

US3122085

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 20:03:21

US3122085

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 20:03:21

US3122085

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 20:03:27

US3122085

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Apr 2021 20:03:27

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:22:03

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:17:49
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '18 Nov 2020'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:05:42

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:22:03

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:17:49
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '14:06'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:05:42

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:22:03

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:17:49
User entered '18 Nov 2020 14:06'	System	17 Dec 2020 18:05:42

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:22:03

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:17:49
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:05:42

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:22:03

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:17:49
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:05:42

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:22:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:17:49
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:08:12

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:22:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:17:49
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '18 Nov 2020'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:08:12

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:22:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:17:49
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:08:12

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:22:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:17:49
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '97'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:08:12

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:22:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:17:49
User entered '%'	System	17 Dec 2020 18:08:12

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:22:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:17:49
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:08:12

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:22:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:17:49
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:08:12

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:22:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:17:49
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:08:12

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:22:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:17:49
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:08:12

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:22:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:17:49
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:08:12

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:22:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:17:49
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:08:12

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:22:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:17:49
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:08:12

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:22:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:17:49
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:08:12

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:22:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:17:49
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:08:12

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:22:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:17:49
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:08:12

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:22:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:17:49
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:08:12

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:22:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:17:49
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:08:12

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:22:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:17:49
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:08:12

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:22:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:17:49
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:08:12

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:22:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:17:49
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:08:12

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:22:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:17:49
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:08:12

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:22:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:17:49
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:08:12

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:22:03

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:17:49
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '18 Nov 2020'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:12:35

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:22:03

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:17:49
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:12:35

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:22:03

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:17:49
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:12:35

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:22:03

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:17:49
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '18 Nov 2020'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:12:35

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:22:03

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:17:49
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	17 Dec 2020 18:12:35

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:22:03

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:17:49
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:12:35

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:22:03

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:17:49
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:12:35

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:22:03

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:17:49
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:12:35

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:22:03

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:17:49
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:12:35

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:22:03

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:17:49
User entered '0'	System	17 Dec 2020 18:12:35

US3122085

Folder: Covid-19 Assessment 18 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:22:03

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:17:49
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:08:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:49:27

US3122085

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:22:03

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User accepted default value 'Day 3 (Day 3)'		17 Mar 2021 15:49:42

US3122085

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:22:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:08:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:49:42

US3122085

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:22:03

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:08:37
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:49:42

US3122085

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:22:03

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User accepted default value 'Day 5 (Day 5)'		17 Mar 2021 15:49:42

US3122085

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:22:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:08:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:49:42

US3122085

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:22:03

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:08:37
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:49:42

US3122085

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:22:03

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User accepted default value 'Day 7 (Day 7)'		17 Mar 2021 15:49:42

US3122085

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:22:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:08:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:49:42

US3122085

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:22:03

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:08:37
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:49:42

US3122085

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:22:03

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User accepted default value 'Day 9 (Day 9)'		17 Mar 2021 15:49:42

US3122085

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:22:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:08:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:49:42

US3122085

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:22:03

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:08:37
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:49:42

US3122085

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:22:03

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User accepted default value 'Day 14 (Day 14)'		17 Mar 2021 15:49:42

US3122085

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:22:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:08:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:49:42

US3122085

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:22:03

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:08:37
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:49:42

US3122085

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:22:03

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User accepted default value 'Day 21 (Day 21)'		17 Mar 2021 15:49:42

US3122085

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:22:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:08:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:49:42

US3122085

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:22:03

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:08:37
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:49:42

US3122085

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:22:03

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User accepted default value 'Day 28 (Day 28)'		17 Mar 2021 15:49:42

US3122085

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:22:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:08:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:49:42

US3122085

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:22:03

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:08:37
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:49:42

US3122085

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:22:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	23 Nov 2020 20:30:12

US3122085

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:22:03

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 18NOV2020 is reported under Illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 06:17:31
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 18NOV2020 is reported under Illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'This has been added underneath COVID-19 Assessments. ' (Site from DM).		17 Dec 2020 18:15:48
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 18NOV2020 is reported under Illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).		26 Nov 2020 08:40:42
User entered '18 Nov 2020'	Leah Corts (b) (4)	23 Nov 2020 20:30:12

US3122085

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:22:03

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Clinic (Clinic)'	(b) (4) Leah Corts (b) (4)	23 Nov 2020 20:30:12

US3122085

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:22:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User entered 'SICKD1'	System	23 Nov 2020 20:30:12

US3122085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	23 Nov 2020 20:36:54

US3122085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '18 Nov 2020'	(b) (4) Leah Corts (b) (4)	23 Nov 2020 20:36:54

US3122085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '14:11'	(b) (4) Leah Corts (b) (4)	23 Nov 2020 20:36:54

US3122085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User entered '18 Nov 2020 14:11'	System	23 Nov 2020 20:36:54

US3122085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered missing code ND - Not Done.	(b) (4) Leah Corts (b) (4)	23 Nov 2020 20:36:54
DataPoint set to visible.	System	23 Nov 2020 20:30:12

US3122085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered missing code ND - Not Done.	(b) (4) Leah Corts (b) (4)	23 Nov 2020 20:36:54
DataPoint set to visible.	System	23 Nov 2020 20:30:12

US3122085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
Query 'Per CCG, "ND" should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' canceled (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 15:17:52
User opened query 'Per CCG, "ND" should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).		27 Nov 2020 15:22:14
User entered '97.1' F	Leah Corts (b) (4)	23 Nov 2020 20:36:54

US3122085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Oral (Oral)'	(b) (4) Leah Corts (b) (4)	23 Nov 2020 20:36:54

US3122085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) Leah Corts (b) (4)	23 Nov 2020 20:36:54

US3122085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '66'	(b) (4) Leah Corts (b) (4)	23 Nov 2020 20:36:54

US3122085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User entered 'bpm'	System	23 Nov 2020 20:36:54

US3122085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '12'	(b) (4) Leah Corts (b) (4)	23 Nov 2020 20:36:54

US3122085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User entered 'breaths/min'	System	23 Nov 2020 20:36:54

US3122085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '129'	(b) (4) Leah Corts (b) (4)	23 Nov 2020 20:36:54

US3122085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User entered 'mmHg'	System	23 Nov 2020 20:36:54

US3122085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '81'	(b) (4) Leah Corts (b) (4)	23 Nov 2020 20:36:54

US3122085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User entered 'mmHg'	System	23 Nov 2020 20:36:54

US3122085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36

US3122085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36

US3122085

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:22:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	23 Nov 2020 20:37:16

US3122085

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:22:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '18 Nov 2020'	(b) (4) Leah Corts (b) (4)	23 Nov 2020 20:37:16

US3122085

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:22:03

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	23 Nov 2020 20:37:34

US3122085

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:22:03

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '18 Nov 2020'	(b) (4) Leah Corts (b) (4)	23 Nov 2020 20:37:34

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:22:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User closed query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).		25 Mar 2021 15:32:49
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (blood work, CT scan, diagnostic on 09Jan2020). Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342 If no results are available, please confirm in your response.' (Site from Safety).		25 Mar 2021 15:32:46
User closed query 'PV Query: Since the subject was hospitalized for the event of diverticulitis with GI bleed, appropriate grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain.' (Site from Safety).		25 Mar 2021 15:32:43
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).		25 Mar 2021 15:32:37
User closed query 'PV Query: As the last dose of Placebo was given on 26 Aug 2020, please update the action taken with Placebo from none to not applicable.' (Site from Safety).		25 Mar 2021 15:32:34
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:49
Query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' answered with 'This is a duplicate query. Please attach to the area that you are querying next time' (Site from Safety).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:53:13

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:22:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (blood work, CT scan, diagnostic on 09Jan2020). Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'This is a duplicate query. Please attach to the area that you are querying next time' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 13:53:09
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'This is a duplicate query. Please attach to the area that you are querying next time' (Site from Safety).		22 Mar 2021 13:53:04
Query 'PV Query: Since the subject was hospitalized for the event of diverticulitis with GI bleed, appropriate grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain.' answered with 'This is a duplicate query. Please attach to the visit or information that you are querying in the future' (Site from Safety).		22 Mar 2021 13:50:12
Query 'PV Query: As the last dose of Placebo was given on 26 Aug 2020, please update the action taken with Placebo from none to not applicable.' answered with 'done' (Site from Safety).		22 Mar 2021 13:48:13
User closed query 'PV Query: The subject reported an SAE at this visit. Please add SAE to the EDC as soon as possible. Please update the EDC with the information from the paper SAE form including its relevant details, hospitalization details and course of event.' (Site from Safety).		05 Mar 2021 02:22:43
Query 'PV Query: The subject reported an SAE at this visit. Please add SAE to the EDC as soon as possible. Please update the EDC with the information from the paper SAE form including its relevant details, hospitalization details and course of event.' answered with 'AE added' (Site from Safety).	Leah Corts (b) (4)	22 Feb 2021 17:24:17

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:22:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 15:07:26
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (blood work, CT scan, diagnostic on 09Jan2020). Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).		16 Feb 2021 15:07:07
User opened query 'PV Query: Since the subject was hospitalized for the event of diverticulitis with GI bleed, appropriate grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain.' (Site from Safety).		16 Feb 2021 15:06:50
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).		16 Feb 2021 15:06:30
User opened query 'PV Query: As the last dose of Placebo was given on 26 Aug 2020, please update the action taken with Placebo from none to not applicable.' (Site from Safety).		16 Feb 2021 15:06:12
User opened query 'PV Query: The subject reported an SAE at this visit. Please add SAE to the EDC as soon as possible. Please update the EDC with the information from the paper SAE form including its relevant details, hospitalization details and course of event.' (Site from Safety).		16 Feb 2021 15:05:39
User entered 'Yes (Y)'		14 Jan 2021 16:39:20

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:22:03

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:49
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:39:20

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:22:03

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:49
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:39:20

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:22:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User entered 'UNBLND_DECIDE'	System	14 Jan 2021 16:39:20

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:22:03

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:39:42

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:22:03

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:49
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:39:31
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 10:42:07

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:22:03

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:39:42

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:22:03

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:49
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:39:31
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 10:42:07

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:22:03

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:39:42

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:22:03

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:39:42

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:22:03

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 05:39:48
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	14 Jan 2021 16:39:42

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:22:03

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 05:39:48
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	14 Jan 2021 16:39:42

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:22:03

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:39:42

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:22:03

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User entered '1'	System	14 Jan 2021 16:39:42

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:22:03

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User entered 'I'	System	14 Jan 2021 16:39:42

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:22:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:41:58

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:22:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:41:58

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:22:03

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User entered empty.	System	14 Jan 2021 16:41:58
DataPoint set to visible.	System	14 Jan 2021 16:39:42

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:22:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:41:58

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:22:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:41:58

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:22:03

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User entered empty.	System	14 Jan 2021 16:41:58
DataPoint set to visible.	System	14 Jan 2021 16:39:42

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User accepted default value 'Pre-Dose (PREDOSE)'		14 Jan 2021 16:41:58

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:41:58

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:41:58

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '10:20'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:41:58

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User entered '14 Jan 2021 10:20'	System	14 Jan 2021 16:41:58

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:41:58

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:41:58

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:41:58

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '60'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:41:58

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User entered 'bpm'	System	14 Jan 2021 16:41:58

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '16'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:41:58

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User entered 'breaths/min'	System	14 Jan 2021 16:41:58

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '111'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:41:58

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User entered 'mmHg'	System	14 Jan 2021 16:41:58

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '68'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:41:58

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User entered 'mmHg'	System	14 Jan 2021 16:41:58

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:22:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:41:58

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:22:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:41:58

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:22:03

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User entered empty.	System	14 Jan 2021 16:41:58
DataPoint set to visible.	System	14 Jan 2021 16:39:42

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User accepted default value 'Post-Dose (POSTDOSE)'		14 Jan 2021 16:41:58

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:41:58

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:41:58

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '11:34'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:41:58

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User entered '14 Jan 2021 11:34'	System	14 Jan 2021 16:41:58

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:41:58

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:41:58

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:41:58

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '79'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:41:58

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User entered 'bpm'	System	14 Jan 2021 16:41:58

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '16'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:41:58

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User entered 'breaths/min'	System	14 Jan 2021 16:41:58

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '103'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:41:58

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User entered 'mmHg'	System	14 Jan 2021 16:41:58

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '69'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:41:58

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User entered 'mmHg'	System	14 Jan 2021 16:41:58

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:22:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:42:15

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:22:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:42:15

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:43:08

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:43:08

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

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)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:43:08

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User entered 'mRNA-1273'	System	14 Jan 2021 16:43:08
DataPoint set to visible.	System	14 Jan 2021 16:39:42

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:43:08

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '11:00'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:43:08

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User entered '14 Jan 2021 11:00'	System	14 Jan 2021 16:43:08

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:43:08

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User entered 'ONCE'	System	14 Jan 2021 16:43:08

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User entered 'INTRAMUSCULAR'	System	14 Jan 2021 16:43:08

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:22:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:43:38

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:22:03

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:43:38

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:22:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '10:49'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:43:38

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:22:03

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User entered '14 Jan 2021 10:49'	System	14 Jan 2021 16:43:38

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:22:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:44:01

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:22:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:44:01

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:22:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '10:50'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:44:01

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:22:03

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User entered '14 Jan 2021 10:50'	System	14 Jan 2021 16:44:01

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:44:06

US3122085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User entered '1'	System	14 Jan 2021 16:44:06

US3122085

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:39:28

US3122085

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:39:28

US3122085

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:39:28

US3122085

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:39:28

US3122085

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:56:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:40:50

US3122085

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User entered 'I'	System	21 Jan 2021 19:40:50

US3122085

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User entered '1'	System	21 Jan 2021 19:40:50
DataPoint set to visible.	System	21 Jan 2021 19:40:50

US3122085

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:22:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 04FEB2021 is reported under OL-D29 visit in PPD Central lab. Please review if the sample has been collected then update the details under "Unscheduled Visit" on Immunogenicity Assessment page and confirm the correct visit as "Unscheduled" to be updated in the GCL records.' (Site from DM).		19 Apr 2021 13:30:07
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 04FEB2021 is reported under OL-D29 visit in PPD Central lab. Please review if the sample has been collected then update the details under "Unscheduled Visit" on Immunogenicity Assessment page and confirm the correct visit as "Unscheduled" to be updated in the GCL records.' answered with 'Samples are for V4D209. Change request has been submitted to Preclarus' (Site from DM).		16 Apr 2021 20:16:47
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 04FEB2021 is reported under OL-D29 visit in PPD Central lab. Please review if the sample has been collected then update the details under "Unscheduled Visit" on Immunogenicity Assessment page and confirm the correct visit as "Unscheduled" to be updated in the GCL records.' (Site from DM).		16 Apr 2021 08:22:18
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 13:18:21

US3122085

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:22:03

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 13:18:21

US3122085

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:22:03

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 13:18:21

US3122085

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:22:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User entered 'OLD29'	System	11 Mar 2021 13:18:21

US3122085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User accepted default value 'Pre-Dose (PREDOSE)'		11 Mar 2021 13:20:29

US3122085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 13:20:29

US3122085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 13:20:29

US3122085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered '10:11'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 13:20:29

US3122085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User entered '15 Feb 2021 10:11'	System	11 Mar 2021 13:20:29

US3122085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered '36.4' C	(b) (4) (b) (4), (b) (6)	11 Mar 2021 13:20:29

US3122085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 13:20:29

US3122085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 13:20:29

US3122085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered '61'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 13:20:29

US3122085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User entered 'bpm'	System	11 Mar 2021 13:20:29

US3122085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered '16'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 13:20:29

US3122085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User entered 'breaths/min'	System	11 Mar 2021 13:20:29

US3122085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered '125'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 13:20:29

US3122085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User entered 'mmHg'	System	11 Mar 2021 13:20:29

US3122085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered '87'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 13:20:29

US3122085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:22:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User entered 'mmHg'	System	11 Mar 2021 13:20:29

US3122085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User accepted default value 'Post-Dose (POSTDOSE)'		11 Mar 2021 13:20:29

US3122085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 13:20:29

US3122085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 13:20:29

US3122085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered '11:44'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 13:20:29

US3122085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User entered '15 Feb 2021 11:44'	System	11 Mar 2021 13:20:29

US3122085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered '36.6' C	(b) (4) (b) (4), (b) (6)	11 Mar 2021 13:20:29

US3122085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 13:20:29

US3122085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 13:20:29

US3122085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered '53'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 13:20:29

US3122085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User entered 'bpm'	System	11 Mar 2021 13:20:29

US3122085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered '16'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 13:20:29

US3122085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User entered 'breaths/min'	System	11 Mar 2021 13:20:29

US3122085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered '138'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 13:20:29

US3122085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User entered 'mmHg'	System	11 Mar 2021 13:20:29

US3122085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered '83'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 13:20:29

US3122085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:22:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User entered 'mmHg'	System	11 Mar 2021 13:20:29

US3122085

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:22:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 13:20:47

US3122085

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:22:03

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 13:20:47

US3122085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 13:21:16

US3122085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 13:21:16

US3122085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

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)	25 Apr 2021 06:35:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 13:21:16

US3122085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User entered 'mRNA-1273'	System	11 Mar 2021 13:21:16
DataPoint set to visible.	System	21 Jan 2021 19:40:50

US3122085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 13:21:16

US3122085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered '10:48'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 13:21:16

US3122085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User entered '15 Feb 2021 10:48'	System	11 Mar 2021 13:21:16

US3122085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 13:21:16

US3122085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User entered 'ONCE'	System	11 Mar 2021 13:21:16

US3122085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:22:03

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User entered 'INTRAMUSCULAR'	System	11 Mar 2021 13:21:16

US3122085

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 13:21:24

US3122085

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User entered 'I'	System	11 Mar 2021 13:21:24

US3122085

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:08:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:58:34

US3122085

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:08:37
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:58:34

US3122085

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:08:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:58:34

US3122085

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:22:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:08:37
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:58:34

US3122085

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:08:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:42:25

US3122085

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:22:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User entered 'I'	System	17 Mar 2021 15:42:25

US3122085

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:22:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:08:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:42:47

US3122085

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:22:03

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:08:37
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:42:47

US3122085

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:22:03

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:08:37
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:42:47

US3122085

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:22:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User entered 'OLD57'	System	17 Mar 2021 15:42:47

US3122085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:08:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:43:44

US3122085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:08:37
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:43:44

US3122085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:08:37
User entered '11:10'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:43:44

US3122085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User entered '17 Mar 2021 11:10'	System	17 Mar 2021 15:43:44

US3122085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:08:37
User entered '36.6' C	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:43:44

US3122085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:08:37
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:43:44

US3122085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:08:37
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:43:44

US3122085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:08:37
User entered '59'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:43:44

US3122085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User entered 'bpm'	System	17 Mar 2021 15:43:44

US3122085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:08:37
User entered '12'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:43:44

US3122085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User entered 'breaths/min'	System	17 Mar 2021 15:43:44

US3122085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:08:37
User entered '119'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:43:44

US3122085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User entered 'mmHg'	System	17 Mar 2021 15:43:44

US3122085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:08:37
User entered '72'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:43:44

US3122085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User entered 'mmHg'	System	17 Mar 2021 15:43:44

US3122085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29

US3122085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:22:03

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29

US3122085

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:22:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:08:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:43:48

US3122085

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:22:03

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:29
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:08:37
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:43:48

US3122085

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:22:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:08:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:44:03

US3122085

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:22:03

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per Preclarus report, Sample recorded under OL-D57 is dated 17MAR2021 is in EDC, however the same is missing in PPD GCL. Please kindly confirm if the sample has been collected and shipped, and if shipped kindly provide barcode #, Accession #, AWB #, Shipping date to track the missing sample. Thank you.' (Site from DM).		19 Apr 2021 08:23:27
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per Preclarus report, Sample recorded under OL-D57 is dated 17MAR2021 is in EDC, however the same is missing in PPD GCL. Please kindly confirm if the sample has been collected and shipped, and if shipped kindly provide barcode #, Accession #, AWB #, Shipping date to track the missing sample. Thank you.' answered with 'On 14 Apr 2021 site staff confirmed that there are no remaining samples on site and that all study samples were shipped; however barcode #, Accession #, AWB #, and Shipping date to track the missing samples were not retained. Sorry for and inconvenience. Please refer to the Preclarus lab report to obtain requested information.' (Site from DM).		14 Apr 2021 13:51:30
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per Preclarus report, Sample recorded under OL-D57 is dated 17MAR2021 is in EDC, however the same is missing in PPD GCL. Please kindly confirm if the sample has been collected and shipped, and if shipped kindly provide barcode #, Accession #, AWB #, Shipping date to track the missing sample. Thank you.' (Site from DM).		08 Apr 2021 06:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:08:37
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:44:03

US3122085

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:22:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:08:37
User entered '11:12'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:44:03

US3122085

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:22:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:28
User entered '17 Mar 2021 11:12'	System	17 Mar 2021 15:44:03

US3122085

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:22:03

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:46:12
DataPoint Verified.		07 Apr 2021 16:26:05
User signature succeeded.	Matthew Hong (b) (4)	22 Feb 2021 15:07:27
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	22 Feb 2021 15:02:33

US3122085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:22:03

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:25:39
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:15
User entered 'USA-US063-2021-mRNA-1273-P301000001'	System	23 Feb 2021 14:21:07
User entered 'New'	(b) (4), (b) (6)	23 Feb 2021 14:21:07

US3122085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:22:03

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:25:39
User signature succeeded.	Matthew Hong (b) (4)	22 Feb 2021 19:28:18
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Diverticulitis, LLT: Diverticulitis - version MedDRA\\23.0.	Coder Import (b) (4)	22 Feb 2021 16:34:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Feb 2021 16:34:01
Data point term sent to Coder	System	22 Feb 2021 16:33:08
User entered 'Diverticulitis'	Leah Corts (b) (4)	22 Feb 2021 16:32:38

US3122085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:22:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:25:39
User signature succeeded.	Matthew Hong (b) (4)	22 Feb 2021 19:28:18
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	22 Feb 2021 16:32:38

US3122085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:22:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:25:39
User signature succeeded.	Matthew Hong (b) (4)	22 Feb 2021 19:28:18
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	22 Feb 2021 16:32:38

US3122085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:22:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:25:39
User closed query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No. ' (Site from Safety). User signature succeeded.	(b) (4)	23 Feb 2021 01:19:47
Query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No. ' answered with 'corrected' (Site from Safety).	Matthew Hong (b) (4)	22 Feb 2021 19:28:18
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
User opened query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No. ' (Site from Safety). User entered 'Yes (Y)'	Leah Corts (b) (4)	22 Feb 2021 18:43:41
	(b) (4)	
	Leah Corts (b) (4)	22 Feb 2021 18:43:27
	(b) (4), (b) (6)	22 Feb 2021 17:32:01
	Leah Corts (b) (4)	22 Feb 2021 16:32:38

US3122085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:22:03

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:25:39
User signature succeeded.	Matthew Hong (b) (4)	22 Feb 2021 19:28:18
User entered '08 Jan 2021'	(b) (4) Leah Corts (b) (4)	22 Feb 2021 16:32:38

US3122085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:22:03

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:25:39
User signature succeeded.	Matthew Hong (b) (4)	22 Feb 2021 19:28:18
User entered empty.	(b) (4) Leah Corts (b) (4)	22 Feb 2021 16:32:38

US3122085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:22:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 16:32:38

US3122085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:22:03

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:25:39
User signature succeeded.	Matthew Hong (b) (4)	22 Feb 2021 19:28:18
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	22 Feb 2021 16:32:38

US3122085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:22:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:25:39
User signature succeeded.	Matthew Hong (b) (4)	22 Feb 2021 19:28:18
User entered '13 Jan 2021'	(b) (4) Leah Corts (b) (4)	22 Feb 2021 16:32:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:22:03

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:25:39
User signature succeeded.	Matthew Hong (b) (4)	22 Feb 2021 19:28:18
User entered empty.	(b) (4) Leah Corts (b) (4)	22 Feb 2021 16:32:38

US3122085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:22:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 16:32:38

US3122085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:22:03

[Severity](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:38:53
DataPoint Verified.		07 Apr 2021 16:25:39
User signature succeeded.	Matthew Hong (b) (4)	23 Mar 2021 19:17:52
User closed query 'PV Query: Since the subject was hospitalized for the event of diverticulitis with GI bleed, appropriate grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain.' (Site from Safety).	(b) (4)	
Query 'PV Query: Since the subject was hospitalized for the event of diverticulitis with GI bleed, appropriate grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 16:24:34
Signature has been broken.		22 Mar 2021 13:58:13
User entered 'Grade 3/Severe (Grade 3/Severe)'		22 Mar 2021 13:52:43
reason for change: Data Entry Error		22 Mar 2021 13:52:43
User opened query 'PV Query: Since the subject was hospitalized for the event of diverticulitis with GI bleed, appropriate grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain.' (Site from Safety).		25 Feb 2021 16:35:29
User signature succeeded.	Matthew Hong (b) (4)	22 Feb 2021 19:28:18
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	
	Leah Corts (b) (4)	22 Feb 2021 16:32:38

US3122085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:22:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:25:39
User signature succeeded.	Matthew Hong (b) (4)	22 Feb 2021 19:28:18
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	22 Feb 2021 16:32:38

US3122085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:22:03

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:25:39
User signature succeeded.	Matthew Hong (b) (4)	22 Feb 2021 19:28:18
User entered '0'	(b) (4) Leah Corts (b) (4)	22 Feb 2021 16:32:38

US3122085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:22:03

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:25:39
User signature succeeded.	Matthew Hong (b) (4)	22 Feb 2021 19:28:18
User entered '0'	(b) (4) Leah Corts (b) (4)	22 Feb 2021 16:32:38

US3122085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:22:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:25:39
User signature succeeded.	Matthew Hong (b) (4)	22 Feb 2021 19:28:18
User entered 'I'	(b) (4) Leah Corts (b) (4)	22 Feb 2021 16:32:38

US3122085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:22:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:25:39
User signature succeeded.	Matthew Hong (b) (4)	22 Feb 2021 19:28:18
User entered '08 Jan 2021'	(b) (4) Leah Corts (b) (4)	22 Feb 2021 16:32:38

US3122085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:22:03

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:25:39
User signature succeeded.	Matthew Hong (b) (4)	22 Feb 2021 19:28:18
User entered '13 Jan 2021'	(b) (4) Leah Corts (b) (4)	22 Feb 2021 16:32:38

US3122085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:22:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:25:39
User signature succeeded.	Matthew Hong (b) (4)	22 Feb 2021 19:28:18
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	22 Feb 2021 16:32:38

US3122085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:22:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:25:39
User signature succeeded.	Matthew Hong (b) (4)	22 Feb 2021 19:28:18
User entered empty.	(b) (4) Leah Corts (b) (4)	22 Feb 2021 16:32:38

US3122085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:22:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:25:39
User signature succeeded.	Matthew Hong (b) (4)	22 Feb 2021 19:28:18
User entered '0'	(b) (4) Leah Corts (b) (4)	22 Feb 2021 16:32:38

US3122085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:22:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:25:39
User signature succeeded.	Matthew Hong (b) (4)	22 Feb 2021 19:28:18
User entered '0'	(b) (4) Leah Corts (b) (4)	22 Feb 2021 16:32:38

US3122085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:22:03

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:25:39
User signature succeeded.	Matthew Hong (b) (4)	22 Feb 2021 19:28:18
User entered '0'	(b) (4) Leah Corts (b) (4)	22 Feb 2021 16:32:38

US3122085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:22:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:25:39
User signature succeeded.	Matthew Hong (b) (4)	22 Feb 2021 19:28:18
User entered 'Not Related (NOT RELATED)'	(b) (4) Leah Corts (b) (4)	22 Feb 2021 16:32:38

US3122085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:22:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:25:39
User signature succeeded.	Matthew Hong (b) (4)	22 Feb 2021 19:28:18
User entered 'Not Related (NOT RELATED)'	(b) (4) Leah Corts (b) (4)	22 Feb 2021 16:32:38

US3122085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:22:03

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:25:39
User signature succeeded.	Matthew Hong (b) (4)	22 Feb 2021 19:28:18
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	22 Feb 2021 17:32:18
reason for change: Data Entry Error	Leah Corts (b) (4)	
User entered 'None (NONE)'	Leah Corts (b) (4)	22 Feb 2021 16:32:38

US3122085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:22:03

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:25:39
User signature succeeded.	Matthew Hong (b) (4)	22 Feb 2021 19:28:18
User entered 'I'	(b) (4) Leah Corts (b) (4)	22 Feb 2021 16:32:38

US3122085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:22:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:25:39
User signature succeeded.	Matthew Hong (b) (4)	22 Feb 2021 19:28:18
User entered '0'	(b) (4) Leah Corts (b) (4)	22 Feb 2021 16:32:38

US3122085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:22:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:25:39
User signature succeeded.	Matthew Hong (b) (4)	22 Feb 2021 19:28:18
User entered '0'	(b) (4) Leah Corts (b) (4)	22 Feb 2021 16:32:38

US3122085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:22:03

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:25:39
User signature succeeded.	Matthew Hong (b) (4)	22 Feb 2021 19:28:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Leah Corts (b) (4)	22 Feb 2021 16:32:38

US3122085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:22:03

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:25:39
User signature succeeded.	Matthew Hong (b) (4)	22 Feb 2021 19:28:18
User entered empty.	(b) (4) Leah Corts (b) (4)	22 Feb 2021 16:32:38

US3122085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:22:03

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative = DIVERTICULITIS WHICH WAS NOTED ON A PREVIOUS COLONOSCOPY AT LEAST 15 YEARS AGO. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 07:40:59
Query 'Per DM CLR: Narrative = DIVERTICULITIS WHICH WAS NOTED ON A PREVIOUS COLONOSCOPY AT LEAST 15 YEARS AGO. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate. ' answered with 'Medical History entry added.' (Site from DM).		12 Apr 2021 14:42:23
DataPoint Verified.		07 Apr 2021 16:25:39
User opened query 'Per DM CLR: Narrative = DIVERTICULITIS WHICH WAS NOTED ON A PREVIOUS COLONOSCOPY AT LEAST 15 YEARS AGO. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate. ' (Site from DM).		30 Mar 2021 12:23:28
Query 'Per DM CLR: Narrative = PREVIOUS COLONOSCOPY AT LEAST 15 YEARS AGO. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate. ' canceled (Site from DM).		30 Mar 2021 12:23:24
User opened query 'Per DM CLR: Narrative = PREVIOUS COLONOSCOPY AT LEAST 15 YEARS AGO. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate. ' (Site from DM).		30 Mar 2021 12:22:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:22:03

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative indicates Bloodwork and CAT Scan was performed. However, there are no recorded Concomitant Procedures record that match the information. Please review and update to record the corresponding procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 08:20:39
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).		23 Mar 2021 16:24:56
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (blood work, CT scan, diagnostic on 09Jan2020). Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).		23 Mar 2021 16:24:50
Query 'Per DM CLR: Narrative indicates Bloodwork and CAT Scan was performed. However, there are no recorded Concomitant Procedures record that match the information. Please review and update to record the corresponding procedures as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).		22 Mar 2021 13:57:50
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (blood work, CT scan, diagnostic on 09Jan2020). Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Request for subjects medical records for their visit was submitted to hospital on 2/22/21. We are waiting for their response' (Site from Safety).		22 Mar 2021 13:56:03

US3122085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:22:03

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'Request for subjects medical records for their visit was submitted to hospital on 2/22/21. We are waiting for their response' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 13:55:51
User opened query 'Per DM CLR: Narrative indicates Bloodwork and CAT Scan was performed. However, there are no recorded Concomitant Procedures record that match the information. Please review and update to record the corresponding procedures as appropriate. Otherwise, clarify.' (Site from DM).		02 Mar 2021 18:55:31
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (blood work, CT scan, diagnostic on 09Jan2020). Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).		25 Feb 2021 16:35:46
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).		25 Feb 2021 16:34:50
User signature succeeded.	Matthew Hong (b) (4)	22 Feb 2021 19:28:18
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	(b) (4) System	22 Feb 2021 17:18:11
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	22 Feb 2021 17:18:11

US3122085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:22:03

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject woke up at 3:30 AM of 08JAN2021 having bright red bloody stools on several occasions. Subject stated he felt light headed and sweaty around 7:00 AM and decided to go to the urgent care who directed subject to go to the Duke Emergency room. Subject was admitted overnight where bloodwork and Cat scan was performed in ER subject states his Hgb was 12 and later dropped to 10 overnight. Subject states that Hgb went back to 11.8 by discharge. On 09JAN2021, showed subject to have diverticulitis which was noted on a previous colonoscopy at least 15 years ago. Per the hospital GI doctors, they told the subject bleeding would stop on its own. Subject was discharged with no medication and received none in ER while admitted.' reason for change: Data Entry Error	Leah Corts (b) (4)	22 Feb 2021 17:18:11
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	22 Feb 2021 16:32:38
User entered empty.	Leah Corts (b) (4)	22 Feb 2021 16:32:38

US3122085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:22:03

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Feb 2021 16:32:38

US3122085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:22:03

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Feb 2021 16:32:38

US3122085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:22:03

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Feb 2021 16:32:38

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:22:03

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:46:12
DataPoint Verified.		07 Apr 2021 16:26:21
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:41:46

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:22:03

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Jul 2020 20:43:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Jul 2020 20:43:10
Data point term sent to Coder	System	31 Jul 2020 20:42:28
User entered 'Omeprazole'	Brad Killebrew (b) (4)	31 Jul 2020 20:42:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:22:03

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'No (N)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:42:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:22:03

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'GERD'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:42:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:22:03

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '40'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:42:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:22:03

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'mg (mg)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:42:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:22:03

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:42:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:22:03

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'once daily (QD)'	Brad Killebrew (b) (4)	31 Jul 2020 20:42:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:22:03

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:42:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:22:03

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Oral (ORAL)'	Brad Killebrew (b) (4)	31 Jul 2020 20:42:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:22:03

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	Brad Killebrew (b) (4)	31 Jul 2020 20:42:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:22:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	03 Aug 2020 14:06:19
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Correct as is' (Site from System).	Brad Killebrew (b) (4)	31 Jul 2020 20:42:32
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	31 Jul 2020 20:42:25
User entered 'un UNK 2000'	Brad Killebrew (b) (4)	31 Jul 2020 20:42:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:22:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:42:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:22:03

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	Brad Killebrew (b) (4)	31 Jul 2020 20:42:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:22:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	Brad Killebrew (b) (4)	31 Jul 2020 20:42:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:22:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'No (N)'	Brad Killebrew (b) (4)	31 Jul 2020 20:42:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:22:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Jul 2020 20:42:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:22:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Jul 2020 20:42:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:22:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Jul 2020 20:42:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:22:03

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Jul 2020 20:44:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Jul 2020 20:44:11
Data point term sent to Coder	System	31 Jul 2020 20:43:30
User entered 'Sertraline'	Brad Killebrew (b) (4)	31 Jul 2020 20:43:24

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:22:03

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'No (N)'	Brad Killebrew (b) (4)	31 Jul 2020 20:43:24

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:22:03

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Depression'	Brad Killebrew (b) (4)	31 Jul 2020 20:43:24

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:22:03

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '25'	Brad Killebrew (b) (4)	31 Jul 2020 20:43:24

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:22:03

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'mg (mg)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:43:24

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:22:03

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	Brad Killebrew (b) (4)	31 Jul 2020 20:43:24

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:22:03

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'once daily (QD)'	Brad Killebrew (b) (4)	31 Jul 2020 20:43:24

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:22:03

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:43:24

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:22:03

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Oral (ORAL)'	Brad Killebrew (b) (4)	31 Jul 2020 20:43:24

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:22:03

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:43:24

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:22:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	03 Aug 2020 14:06:23
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Correct as is' (Site from System).	Brad Killebrew (b) (4)	31 Jul 2020 20:43:40
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	31 Jul 2020 20:43:24
User entered 'un UNK 1995'	Brad Killebrew (b) (4)	31 Jul 2020 20:43:24

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:22:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:43:24

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:22:03

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	Brad Killebrew (b) (4)	31 Jul 2020 20:43:24

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:22:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:43:24

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:22:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'No (N)'	Brad Killebrew (b) (4)	31 Jul 2020 20:43:24

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:22:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Jul 2020 20:43:24

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:22:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Jul 2020 20:43:24

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:22:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Jul 2020 20:43:24

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:22:03

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION HYDROCHLORIDE, PRODUCTSYNONYM: WELLBUTRIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	31 Jul 2020 20:45:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Jul 2020 20:45:09
Data point term sent to Coder	System	31 Jul 2020 20:44:34
User entered 'Wellbutrin'	Brad Killebrew (b) (4)	31 Jul 2020 20:44:27

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:22:03

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'No (N)'	Brad Killebrew (b) (4)	31 Jul 2020 20:44:27

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:22:03

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Depression'	Brad Killebrew (b) (4)	31 Jul 2020 20:44:27

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:22:03

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '300'	Brad Killebrew (b) (4)	31 Jul 2020 20:44:27

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:22:03

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'mg (mg)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:44:27

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:22:03

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:44:27

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:22:03

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'once daily (QD)'	Brad Killebrew (b) (4)	31 Jul 2020 20:44:27

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:22:03

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:44:27

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:22:03

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Oral (ORAL)'	Brad Killebrew (b) (4)	31 Jul 2020 20:44:27

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:22:03

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:44:27

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:22:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	03 Aug 2020 14:06:26
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Brad Killebrew (b) (4)	31 Jul 2020 20:44:32
answered with 'Correct as is' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	31 Jul 2020 20:44:27
User entered 'un UNK 2005'	Brad Killebrew (b) (4)	31 Jul 2020 20:44:27

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:22:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:44:27

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:22:03

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:44:27

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:22:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:44:27

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:22:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'No (N)'	Brad Killebrew (b) (4)	31 Jul 2020 20:44:27

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:22:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Jul 2020 20:44:27

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:22:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Jul 2020 20:44:27

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:22:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Jul 2020 20:44:27

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:22:03

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Jul 2020 20:46:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Jul 2020 20:46:11
Data point term sent to Coder	System	31 Jul 2020 20:45:34
User entered 'Metoprolol'	Brad Killebrew (b) (4)	31 Jul 2020 20:45:18

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:22:03

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'No (N)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:45:18

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:22:03

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Hypertension'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:45:18

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:22:03

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '100'	Brad Killebrew (b) (4)	31 Jul 2020 20:45:18

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:22:03

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'mg (mg)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:45:18

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:22:03

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:45:18

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:22:03

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'once daily (QD)'	Brad Killebrew (b) (4)	31 Jul 2020 20:45:18

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:22:03

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:45:18

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:22:03

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Oral (ORAL)'	Brad Killebrew (b) (4)	31 Jul 2020 20:45:18

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:22:03

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:45:18

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:22:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	03 Aug 2020 14:06:30
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Correct as is' (Site from System).	Brad Killebrew (b) (4)	31 Jul 2020 20:45:25
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	31 Jul 2020 20:45:18
User entered 'un UNK 2000'	Brad Killebrew (b) (4)	31 Jul 2020 20:45:18

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:22:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:45:18

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:22:03

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	Brad Killebrew (b) (4)	31 Jul 2020 20:45:18

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:22:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	Brad Killebrew (b) (4)	31 Jul 2020 20:45:18

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:22:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'No (N)'	Brad Killebrew (b) (4)	31 Jul 2020 20:45:18

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:22:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Jul 2020 20:45:18

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:22:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Jul 2020 20:45:18

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:22:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Jul 2020 20:45:18

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:22:03

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Jul 2020 20:47:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Jul 2020 20:47:11
Data point term sent to Coder	System	31 Jul 2020 20:46:35
User entered 'Simvastatin'	Brad Killebrew (b) (4)	31 Jul 2020 20:46:28

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:22:03

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'No (N)'	Brad Killebrew (b) (4)	31 Jul 2020 20:46:28

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:22:03

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Hyperlipidemia'	Brad Killebrew (b) (4)	31 Jul 2020 20:46:28

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:22:03

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '80'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:46:28

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:22:03

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'mg (mg)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:46:28

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:22:03

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:46:28

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:22:03

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'once daily (QD)'	Brad Killebrew (b) (4)	31 Jul 2020 20:46:28

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:22:03

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:46:28

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:22:03

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Oral (ORAL)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:46:28

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:22:03

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:46:28

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:22:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	03 Aug 2020 14:06:34
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Correct as is' (Site from System).	Brad Killebrew (b) (4)	31 Jul 2020 20:46:35
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	31 Jul 2020 20:46:28
User entered 'un UNK 2005'	Brad Killebrew (b) (4)	31 Jul 2020 20:46:28

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:22:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:46:28

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:22:03

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	Brad Killebrew (b) (4)	31 Jul 2020 20:46:28

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:22:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:46:28

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:22:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'No (N)'	Brad Killebrew (b) (4)	31 Jul 2020 20:46:28

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:22:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Jul 2020 20:46:28

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:22:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Jul 2020 20:46:28

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:22:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Jul 2020 20:46:28

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:22:03

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: EZETIMIBE, PRODUCTSYNONYM: ZETIA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Jul 2020 20:48:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Jul 2020 20:48:12
Data point term sent to Coder	System	31 Jul 2020 20:47:38
User entered 'Zetia'	Brad Killebrew (b) (4)	31 Jul 2020 20:47:13

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:22:03

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'No (N)'	Brad Killebrew (b) (4)	31 Jul 2020 20:47:13

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:22:03

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Hyperlipidemia'	Brad Killebrew (b) (4)	31 Jul 2020 20:47:13

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:22:03

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '10'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:47:13

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:22:03

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'mg (mg)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:47:13

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:22:03

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:47:13

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:22:03

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'once daily (QD)'	Brad Killebrew (b) (4)	31 Jul 2020 20:47:13

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:22:03

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:47:13

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:22:03

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Oral (ORAL)'	Brad Killebrew (b) (4)	31 Jul 2020 20:47:13

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:22:03

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:47:13

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:22:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	03 Aug 2020 14:06:40
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Correct as is' (Site from System).	Brad Killebrew (b) (4)	31 Jul 2020 20:47:19
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	31 Jul 2020 20:47:13
User entered 'un UNK 2005'	Brad Killebrew (b) (4)	31 Jul 2020 20:47:13

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:22:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:47:13

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:22:03

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:47:13

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:22:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	Brad Killebrew (b) (4)	31 Jul 2020 20:47:13

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:22:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'No (N)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:47:13

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:22:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Jul 2020 20:47:13

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:22:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Jul 2020 20:47:13

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:22:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Jul 2020 20:47:13

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:22:03

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTI-ACNE PREPARATIONS, ATC: ANTI-ACNE PREPARATIONS FOR TOPICAL USE, ATC: ANTIINFECTIVES FOR TREATMENT OF ACNE, PRODUCT: SULFACETAMIDE SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Sep 2020 10:02:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Sep 2020 10:02:42
Data point term sent to Coder Coding entries removed.	System Leah Corts (b) (4)	17 Sep 2020 15:26:11 17 Sep 2020 15:25:37
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTI-ACNE PREPARATIONS, ATC: ANTI-ACNE PREPARATIONS FOR TOPICAL USE, ATC: ANTIINFECTIVES FOR TREATMENT OF ACNE, PRODUCT: SULFACETAMIDE SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Sep 2020 08:19:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Sep 2020 08:19:55
Data point term sent to Coder User entered 'Sodium Sulfatamide'	System Brad Killebrew (b) (4)	31 Jul 2020 20:49:39 31 Jul 2020 20:48:39

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:22:03

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'No (N)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:48:39

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:22:03

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User closed query 'Per DM CLR: Please update the indication to reflect the location of ROSACEA (e.g Generalized or localized-specify part). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:44:24
Query 'Per DM CLR: Please update the indication to reflect the location of ROSACEA (e.g Generalized or localized-specify part). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'clarified' (Site from DM).	Leah Cortis (b) (4)	17 Sep 2020 15:25:44
User entered 'ROSACEA - face' reason for change: Data Entry Error	Leah Cortis (b) (4)	17 Sep 2020 15:25:37
User opened query 'Per DM CLR: Please update the indication to reflect the location of ROSACEA (e.g Generalized or localized-specify part). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 06:11:30
User entered 'Rosacea'	Brad Killebrew (b) (4)	31 Jul 2020 20:48:39

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:22:03

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'I'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:48:39

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:22:03

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Other (OTHER)'	Brad Killebrew (b) (4)	31 Jul 2020 20:48:39

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:22:03

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Application'	Brad Killebrew (b) (4)	31 Jul 2020 20:48:39

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:22:03

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'twice daily (BID)'	Brad Killebrew (b) (4)	31 Jul 2020 20:48:39

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:22:03

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:48:39

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:22:03

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Topical (TOPICAL)'	Brad Killebrew (b) (4)	31 Jul 2020 20:48:39

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:22:03

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:48:39

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:22:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	03 Aug 2020 14:06:44
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Brad Killebrew (b) (4)	31 Jul 2020 20:48:45
answered with 'Correct as is' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	31 Jul 2020 20:48:39
User entered 'un UNK 2019'	Brad Killebrew (b) (4)	31 Jul 2020 20:48:39

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:22:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:48:39

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:22:03

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:48:39

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:22:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	Brad Killebrew (b) (4)	31 Jul 2020 20:48:39

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:22:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'No (N)'	Brad Killebrew (b) (4)	31 Jul 2020 20:48:39

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:22:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	31 Jul 2020 20:48:39

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:22:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Jul 2020 20:48:39

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:22:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Jul 2020 20:48:39

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:22:03

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Aug 2020 01:47:14
User coded data point as Term Coded data point by User (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Aug 2020 01:47:14
Data point term sent to Coder	System	31 Jul 2020 20:50:40
User entered 'Aspirin'	Brad Killebrew (b) (4)	31 Jul 2020 20:50:12

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:22:03

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	Brad Killebrew (b) (4)	31 Jul 2020 20:50:12

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:22:03

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Cardiac Health'	Brad Killebrew (b) (4)	31 Jul 2020 20:50:12

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:22:03

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '325'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:50:12

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:22:03

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'mg (mg)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:50:12

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:22:03

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:50:12

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:22:03

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'once daily (QD)'	Brad Killebrew (b) (4)	31 Jul 2020 20:50:12

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:22:03

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:50:12

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:22:03

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Oral (ORAL)'	Brad Killebrew (b) (4)	31 Jul 2020 20:50:12

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:22:03

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:50:12

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:22:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	03 Aug 2020 14:06:48
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Brad Killebrew (b) (4)	31 Jul 2020 20:50:21
answered with 'Correct as is' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	31 Jul 2020 20:50:12
User entered 'un UNK 2019'	Brad Killebrew (b) (4)	31 Jul 2020 20:50:12

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:22:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:50:12

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:22:03

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:50:12

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:22:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	Brad Killebrew (b) (4)	31 Jul 2020 20:50:12

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:22:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'No (N)'	Brad Killebrew (b) (4)	31 Jul 2020 20:50:12

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:22:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Jul 2020 20:50:12

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:22:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Jul 2020 20:50:12

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:22:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Jul 2020 20:50:12

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:22:03

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Jul 2020 20:52:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	31 Jul 2020 20:52:14
Data point term sent to Coder	System	31 Jul 2020 20:51:40
User entered 'Claritin'	Brad Killebrew (b) (4)	31 Jul 2020 20:51:11

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:22:03

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'No (N)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:51:11

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:22:03

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Seasonal Allergies'	Brad Killebrew (b) (4)	31 Jul 2020 20:51:11

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:22:03

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'I'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:51:11

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:22:03

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'tablet (TABLET)'	Brad Killebrew (b) (4)	31 Jul 2020 20:51:11

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:22:03

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:51:11

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:22:03

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'as needed (PRN)'	Brad Killebrew (b) (4)	31 Jul 2020 20:51:11

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:22:03

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:51:11

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:22:03

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Oral (ORAL)'	Brad Killebrew (b) (4)	31 Jul 2020 20:51:11

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:22:03

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:51:11

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:22:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	03 Aug 2020 14:06:52
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Brad Killebrew (b) (4)	31 Jul 2020 20:51:16
answered with 'Correct as is' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	31 Jul 2020 20:51:11
User entered 'un Jun 2020'	Brad Killebrew (b) (4)	31 Jul 2020 20:51:11

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:22:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:51:11

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:22:03

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:51:11

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:22:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:51:11

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:22:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'No (N)'	Brad Killebrew (b) (4)	31 Jul 2020 20:51:11

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:22:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Jul 2020 20:51:11

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:22:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Jul 2020 20:51:11

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:22:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Jul 2020 20:51:11

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:22:03

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: NICOTINAMIDE, PRODUCTSYNONYM: NIACINAMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Sep 2020 10:55:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Sep 2020 10:55:43
Data point term sent to Coder	System	17 Sep 2020 15:27:12
Coding entries removed.	Leah Cortis (b) (4)	17 Sep 2020 15:26:21
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: NICOTINAMIDE, PRODUCTSYNONYM: NIACINAMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 12:53:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 12:53:14
Data point term sent to Coder	System	31 Jul 2020 20:52:43
User entered 'Niacinamide'	Brad Killebrew (b) (4)	31 Jul 2020 20:52:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:22:03

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'No (N)'	Brad Killebrew (b) (4)	31 Jul 2020 20:52:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:22:03

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User closed query 'Per DM CLR: Please update the indication to reflect the location of ROSACEA (e.g Generalized or localized-specify part). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:44:43
Query 'Per DM CLR: Please update the indication to reflect the location of ROSACEA (e.g Generalized or localized-specify part). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' answered with 'clarified' (Site from DM).	Leah Corts (b) (4)	17 Sep 2020 15:27:38
User entered 'ROSACEA - Face' reason for change: Data Entry Error	Leah Corts (b) (4)	17 Sep 2020 15:26:21
User opened query 'Per DM CLR: Please update the indication to reflect the location of ROSACEA (e.g Generalized or localized-specify part). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 06:10:56
User entered 'Rosacea'	Brad Killebrew (b) (4)	31 Jul 2020 20:52:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:22:03

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User closed 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).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:06:43
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. ' answered with 'clarified' (Site from DM).	Leah Corts (b) (4)	28 Sep 2020 15:32:33
User entered '500' reason for change: Data Entry Error	Leah Corts (b) (4)	28 Sep 2020 15:32:25
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).	(b) (4), (b) (6)	07 Sep 2020 06:11:06
User entered '1'	Brad Killebrew (b) (4)	31 Jul 2020 20:52:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:22:03

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4) Leah Corts (b) (4)	28 Sep 2020 15:32:25
User entered 'tablet (TABLET)'	Brad Killebrew (b) (4)	31 Jul 2020 20:52:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:22:03

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	Brad Killebrew (b) (4)	31 Jul 2020 20:52:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:22:03

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'once daily (QD)'	Brad Killebrew (b) (4)	31 Jul 2020 20:52:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:22:03

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:52:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:22:03

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Oral (ORAL)'	Brad Killebrew (b) (4)	31 Jul 2020 20:52:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:22:03

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	Brad Killebrew (b) (4)	31 Jul 2020 20:52:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:22:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	03 Aug 2020 14:06:57
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Correct as is' (Site from System).	Brad Killebrew (b) (4)	31 Jul 2020 20:52:33
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	31 Jul 2020 20:52:25
User entered 'un UNK 2019'	Brad Killebrew (b) (4)	31 Jul 2020 20:52:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:22:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered '0'	Brad Killebrew (b) (4)	31 Jul 2020 20:52:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:22:03

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'Yes (Y)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:52:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:22:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 20:52:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:22:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:55:57
User entered 'No (N)'	Brad Killebrew (b) (4)	31 Jul 2020 20:52:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:22:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Jul 2020 20:52:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:22:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Jul 2020 20:52:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:22:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Jul 2020 20:52:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:22:03

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 12:39:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 12:39:58
Data point term sent to Coder	System	12 Apr 2021 12:31:18
Coding entries removed.	(b) (4), (b) (6)	12 Apr 2021 12:30:53
DataPoint Verified.		07 Apr 2021 16:26:31
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 09:22:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 09:22:51
User signature succeeded.	Matthew Hong (b) (4) (b) (4)	24 Mar 2021 18:31:07
Data point term sent to Coder	System	23 Mar 2021 20:58:39
User entered 'Monteleukast Na'	(b) (4), (b) (6)	23 Mar 2021 20:58:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:22:03

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Mar 2021 20:58:34
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 20:58:34
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 20:58:25
User entered empty.	(b) (4), (b) (6)	23 Mar 2021 20:58:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:22:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	14 Apr 2021 19:41:46
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of ALLERGIES, (e.g SEASONAL ALLERGIES, FOOD ALLERGY, DRUG ALLERGY etc). Review and update indication and ensure to update/reconcile with MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 19:38:14
Query 'Per DM CLR: Please update the indication to reflect the location and type of ALLERGIES, (e.g SEASONAL ALLERGIES, FOOD ALLERGY, DRUG ALLERGY etc). Review and update indication and ensure to update/reconcile with MH/Adverse event eCRF as appropriate. ' answered with 'updated.' (Site from DM).		12 Apr 2021 12:31:18
DataPoint Un-verified.		12 Apr 2021 12:30:53
Signature has been broken.		12 Apr 2021 12:30:53
User entered 'Seasonal ALLERGIES' reason for change: Data Entry Error		12 Apr 2021 12:30:53
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of ALLERGIES, (e.g SEASONAL ALLERGIES, FOOD ALLERGY, DRUG ALLERGY etc). Review and update indication and ensure to update/reconcile with MH/Adverse event eCRF as appropriate. ' (Site from DM).		10 Apr 2021 07:37:09
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'Allergies'	(b) (4), (b) (6)	23 Mar 2021 20:58:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:22:03

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered '10'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 20:58:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:22:03

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 20:58:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:22:03

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 20:58:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:22:03

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 20:58:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:22:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 20:58:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:22:03

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 20:58:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:22:03

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 20:58:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:22:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered '10 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 20:58:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:22:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 20:58:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:22:03

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 20:58:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:22:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 20:58:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:22:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Mar 2021 20:58:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Mar 2021 20:58:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 20:58:40
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 20:58:25
User entered empty.	(b) (4), (b) (6)	23 Mar 2021 20:58:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:22:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 20:58:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:22:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 20:58:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:22:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Mar 2021 20:58:25

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:22:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:04
DataPoint Verified.	(b) (4)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE RGE (CHO), PRODUCTSYNONYM: SHINGRIX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Mar 2021 09:15:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 09:15:30
Data point term sent to Coder	System	23 Mar 2021 21:03:49
User entered 'Shingrex dose 1'	(b) (4), (b) (6)	23 Mar 2021 21:03:40

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:22:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:04
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:03:40

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:22:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:04
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'Shingles prevention'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:03:40

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:22:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:04
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered '0.5'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:03:40

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:22:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:04
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:03:40

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:22:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:04
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:03:40

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:22:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:04
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:03:40

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:22:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:04
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:03:40

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:22:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:04
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:03:40

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:22:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:04
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:03:40

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:22:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:04
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered '17 Nov 2020'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:03:40

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:22:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:04
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:03:40

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:22:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:04
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:03:40

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:22:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:04
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered '17 Nov 2020'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:03:40

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:22:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:04
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:03:40

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:22:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:04
User entered empty.	System	23 Mar 2021 21:03:40

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:22:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:04
User entered empty.	System	23 Mar 2021 21:03:40

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:22:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:04
User entered empty.	System	23 Mar 2021 21:03:40

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:22:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:07
DataPoint Verified.	(b) (4)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE RGE (CHO), PRODUCTSYNONYM: SHINGRIX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Mar 2021 09:14:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 09:14:31
Data point term sent to Coder	System	23 Mar 2021 21:05:51
User entered 'Shingrex dose 2'	(b) (4), (b) (6)	23 Mar 2021 21:04:56

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:22:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:07
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:04:56

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:22:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:07
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'Shingles prevention'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:04:56

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:22:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:07
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered '0.5'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:04:56

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:22:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:07
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:04:56

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:22:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:07
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:04:56

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:22:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:07
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:04:56

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:22:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:07
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:04:56

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:22:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:07
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:04:56

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:22:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:07
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:04:56

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:22:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:07
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:04:56

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:22:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:07
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:04:56

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:22:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:07
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:04:56

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:22:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:07
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:04:56

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:22:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:07
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:04:56

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:22:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:07
User entered empty.	System	23 Mar 2021 21:04:56

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:22:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:07
User entered empty.	System	23 Mar 2021 21:04:56

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:22:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:07
User entered empty.	System	23 Mar 2021 21:04:56

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:22:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:13
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
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.	(b) (4) Coder Import (b) (4) (b) (4)	23 Mar 2021 21:23:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 21:23:46
Data point term sent to Coder	System	23 Mar 2021 21:07:53
User entered 'Flu shot'	(b) (4), (b) (6)	23 Mar 2021 21:07:09

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:22:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:13
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:07:09

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:22:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:13
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'Flu prevention'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:07:09

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:22:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:13
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'l'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:07:09

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:22:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:13
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:07:09

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:22:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:13
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'Injection'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:07:09

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:22:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:13
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:07:09

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:22:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:13
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:07:09

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:22:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:13
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:07:09

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:22:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:13
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:07:09

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:22:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:13
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered '17 Nov 2020'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:07:09

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:22:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:13
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:07:09

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:22:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:13
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:07:09

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:22:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:13
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered '17 Nov 2020'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:07:09

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:22:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:13
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:07:09

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:22:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:13
User entered empty.	System	23 Mar 2021 21:07:09

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:22:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:13
User entered empty.	System	23 Mar 2021 21:07:09

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:22:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:13
User entered empty.	System	23 Mar 2021 21:07:09

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:22:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:16
DataPoint Verified.	(b) (4)	07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: TETANUS VACCINES, PRODUCT: TETANUS VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Mar 2021 21:10:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Mar 2021 21:10:43
Data point term sent to Coder	System	23 Mar 2021 21:09:57
User entered 'Tetanus shot'	(b) (4), (b) (6)	23 Mar 2021 21:09:04

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:22:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:16
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:09:04

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:22:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:16
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'Tetanus prevention'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:09:04

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:22:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:16
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'l'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:09:04

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:22:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:16
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:09:04

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:22:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:16
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'Injection'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:09:04

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:22:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:16
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:09:04

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:22:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:16
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:09:04

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:22:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:16
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:09:04

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:22:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:16
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:09:04

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:22:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:16
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:09:04

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:22:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:16
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:09:04

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:22:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:16
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:09:04

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:22:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:16
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:09:04

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:22:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:16
DataPoint Verified.		07 Apr 2021 16:26:31
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:09:04

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:22:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:16
User entered empty.	System	23 Mar 2021 21:09:04

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:22:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:16
User entered empty.	System	23 Mar 2021 21:09:04

US3122085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:22:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:22:16
User entered empty.	System	23 Mar 2021 21:09:04

US3122085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:22:03

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:46:12
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:49
Signature has been broken.	(b) (4)	22 Mar 2021 13:56:33
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 13:56:33
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:46
User entered 'No (N)'	(b) (4)	10 Mar 2021 20:18:01
	(b) (4), (b) (6)	

US3122085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:22:03

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:49
User entered '08 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:57:29

US3122085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:22:03

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:49
User entered 'CAT SCAN'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:57:29

US3122085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:22:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:49
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:57:29

US3122085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:22:03

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:49
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:57:29

US3122085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:22:03

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:17:42
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:49
User entered '08 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:57:43

US3122085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:22:03

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:17:42
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:49
User entered 'Bloodwork'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:57:43

US3122085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:22:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:17:42
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:49
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:57:43

US3122085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:22:03

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:17:42
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:49
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:57:43

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'USA-US063-2021-MRNA-1273-P301000001'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'Yes (Y)'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'No (N)'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'No (N)'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'Yes (Y)'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'No (N)'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'No (N)'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'No (N)'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'Wayne'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'Harper'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered '3100 Duraleigh Rd'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'Raleigh'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'NC'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered '27612'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'US'	System	23 Feb 2021 14:21:39

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Mar 2021 16:26:42
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
	(b) (4)	
User entered '1'	System	23 Feb 2021 14:21:39

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'USA-US063-2021-MRNA-1273-P301000001'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'Yes (Y)'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'No (N)'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'No (N)'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'Yes (Y)'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'No (N)'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'No (N)'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'No (N)'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'Wayne'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'Harper'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered '3100 Duraleigh Rd'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'Raleigh'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'NC'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered '27612'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'US'	System	23 Feb 2021 14:21:39

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Mar 2021 16:26:42
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
	(b) (4)	
User entered '1'	System	23 Feb 2021 14:21:39

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:22:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
User entered '23/Feb/2021 09:21'	(b) (4) System	23 Feb 2021 14:21:39

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:22:03

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'I'		23 Feb 2021 14:21:39

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

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[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'USA-US063-2021-MRNA-1273-P301000001'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'Yes (Y)'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'No (N)'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'No (N)'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'Yes (Y)'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'No (N)'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'No (N)'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'No (N)'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'Wayne'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'Harper'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered '3100 Duraleigh Rd'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'Raleigh'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'NC'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered '27612'	System	23 Feb 2021 14:21:07

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:21:45
User entered 'US'	System	23 Feb 2021 14:21:39

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:22:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Mar 2021 16:26:42
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 15:11:19
	(b) (4)	
User entered '1'	System	23 Feb 2021 14:21:39

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:22:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Mar 2021 19:17:52
User entered '23/Mar/2021 12:26'	(b) (4) System	23 Mar 2021 16:26:42

US3122085

Folder: SAE USA-US063-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:22:03

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:24
User signature succeeded.	Matthew Hong (b) (4)	23 Mar 2021 19:17:52
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 16:26:42