US3642086 (Prod: University of California San Diego)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:14:49

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US3642086
Form: Participant Creation
Data signed: (b) (4) **13 Feb 2021 02:41:24**
Generated On: 10 Jun 2021 09:14:49

Participant ID	US3642086

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-2893097

US3642086
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	02 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SCRN

FDA-CBER-2022-1614-2893098

US3642086
Folder: Screening
Form: Demographics
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

Date of Birth (MMM yyyy)	(b) (6) 1980
Age	40
Age Units	YEARS
Age (Derived)	40
Sex	Female ☐
	Male ■
Ethnicity	Hispanic or Latino ■
	Not Hispanic or Latino ☐
	Not Reported ☐
	Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

US3642086
Folder: Screening
Form: Enrollment
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

Date of Informed Consent *(dd MMM yyyy)*	02 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐ Amendment 2 ☐ Amendment 3 ■ Amendment 4 ☐ Amendment 5 ☐
Was participant enrolled in the study?	Yes ■ No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐ Inclusion/Exclusion ☐ Cohort Full ☐ Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐ No ■
If Yes, previous participant number	
Enrollment Trigger	1

FDA-CBER-2022-1614-2893100

US3642086
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

Did the participant meet all eligibility criteria?	Yes ■ No ☐

FDA-CBER-2022-1614-2893101

US3642086
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **13 Feb 2021 02:41:30**
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Were any significant conditions reported?	Yes ■ No ☐

FDA-CBER-2022-1614-2893102

US3642086
Folder: Screening
Form: Medical History (1)
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

Condition	TYPE 2 DIABETES
Start date (dd MMM yyyy)	UN FEB 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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US3642086
Folder: Screening
Form: Medical History (2)
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN FEB 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes ☑ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

US3642086
Folder: Screening
Form: Medical History (3)
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

Condition	HYPERCHOLESTROLEMIA
Start date (dd MMM yyyy)	UN AUG 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-2893105

US3642086
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **13 Feb 2021 02:41:30**
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Were vital signs assessed?	Yes ☑ / No ☐
Date of assessment *(dd MMM yyyy)*	02 SEP 2020
Time of assessment *(00:00-23:59)*	15:10 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 15:10
Height *(xxx.x)*	162 cm
Weight *(xxx.x)*	85.1 kg
BMI *(xxx.x)*	32.42646 kg/m^2
BMI units	KG/M2
Temperature *(xxx.x)*	ND - Not Done
Route of measurement	Oral ☐ / Axillary ☐ / Other ☐
If Other, specify	
Pulse *(xxx)*	ND - Not Done
Pulse units	BPM
Respiratory Rate *(xxx)*	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-2893106

US3642086
Folder: Screening
Form: Physical Examination
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

Was the physical examination performed?	Yes ☑ No ☐
Date of examination *(dd MMM yyyy)*	02 SEP 2020

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

FDA-CBER-2022-1614-2893107

US3642086
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **13 Feb 2021 02:41:30**
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Occupational Risk	
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes ■ No ☐
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes ☐ No ■
Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes ☐ No ■
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes ☐ No ■
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes ☐ No ■
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes ☐ No ■
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes ☐ No ■
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes ☐ No ■
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes ☐ No ■
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes ☐ No ■
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes ☐ No ■
Other	Yes ☐ No ■
Specify	
Location and Living Circumstances Risk (check all that apply)	
No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False

FDA-CBER-2022-1614-2893108

US3642086
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **13 Feb 2021 02:41:30**
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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	

FDA-CBER-2022-1614-2893109

US3642086
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	02 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	VISIT1

FDA-CBER-2022-1614-2893110

US3642086
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **13 Feb 2021 02:41:30**
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What was the date of randomization? *(dd MMM yyyy)*	02 SEP 2020
What was the participant's randomization number?	145359
In what Cohort was the participant enrolled?	>=18 and <65 years and not at risk ☐ >=18 and <65 years and at risk ■ >=65 years ☐

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

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)	Yes ☐ No ■
Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)	Yes ☐ No ■
Severe obesity (body mass index > or = 40kg/m2	Yes ☐ No ■
Diabetes (Type I, Type 2, or gestational)	Yes ■ No ☐
Liver Disease	Yes ☐ No ■
Human Immunodeficiency Virus (HIV) infection	Yes ☐ No ■

FDA-CBER-2022-1614-2893111

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **13 Feb 2021 02:41:30**
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Height	ND - Not Done
Weight	ND - Not Done

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US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	02 SEP 2020
Time of assessment *(00:00-23:59)*	15:10 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 15:10
Temperature *(xxx.x)*	98.7 F
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	TEMPORAL
Pulse *(xxx)*	80 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	90 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-2893113

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	02 SEP 2020
Time of assessment *(00:00-23:59)*	17:11 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 17:11
Temperature *(xxx.x)*	98.5 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	73 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	70 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-2893114

US3642086
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

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.

FDA-CBER-2022-1614-2893115

US3642086
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **13 Feb 2021 02:41:30**
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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)*	02 SEP 2020
What was the treatment time? *(00:00-23:59)*	16:40 (24 HR)
Treatment Date and Time (derived)	02 SEP 2020 16:40
Which arm was used to give treatment?	Left Arm ■ Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

FDA-CBER-2022-1614-2893116

US3642086
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	02 SEP 2020
Collection time *(00:00-23:59)*	15:55 (24 HR)
Collection date and time (derived)	02 SEP 2020 15:55

FDA-CBER-2022-1614-2893117

US3642086
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

Collection date *(dd MMM yyyy)*			02 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:58	02 SEP 2020 15:58
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-2893118

US3642086
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **13 Feb 2021 02:41:30**
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Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2893119

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:14:49

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	02 SEP 2020 17:00
PC Close Date & Time	02 SEP 2020 19:30

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.5 °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	02 SEP 2020 16:58
PC Open Date & Time	02 SEP 2020 14:25
PC Close Date & Time	03 SEP 2020 11:59

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:14:49

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**	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	03 SEP 2020 12:20
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 3

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.2 °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	04 SEP 2020 12:09
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:14:49

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**	98.7 °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	05 SEP 2020 15:19
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

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US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 5

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	06 SEP 2020 18:04
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 6

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.0 °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	07 SEP 2020 17:21
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:14:49

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**	97.9 °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	08 SEP 2020 17:32
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

FDA-CBER-2022-1614-2893127

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:14:49

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	02 SEP 2020 17:00
PC Close Date & Time	02 SEP 2020 19:30

FDA-CBER-2022-1614-2893128

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:14:49

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	02 SEP 2020 16:59
PC Open Date & Time	02 SEP 2020 14:25
PC Close Date & Time	03 SEP 2020 11:59

FDA-CBER-2022-1614-2893129

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 2
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	03 SEP 2020 12:20
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 3
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	04 SEP 2020 12:09
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

FDA-CBER-2022-1614-2893131

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 4
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	05 SEP 2020 15:19
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

FDA-CBER-2022-1614-2893132

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 5
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	06 SEP 2020 18:05
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

FDA-CBER-2022-1614-2893133

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 6
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	07 SEP 2020 17:21
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

FDA-CBER-2022-1614-2893134

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 7
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	08 SEP 2020 17:33
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

FDA-CBER-2022-1614-2893135

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 ☐

FDA-CBER-2022-1614-2893136

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:14:49

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐ Yes ☐
PC Time stamp	
PC Open Date & Time	02 SEP 2020 17:00
PC Close Date & Time	02 SEP 2020 19:30

FDA-CBER-2022-1614-2893137

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 ☐

FDA-CBER-2022-1614-2893138

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:14:49

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	02 SEP 2020 16:59
PC Open Date & Time	02 SEP 2020 14:25
PC Close Date & Time	03 SEP 2020 11:59

FDA-CBER-2022-1614-2893139

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:14:49

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 ■

FDA-CBER-2022-1614-2893140

	Yes ☐
PC Time stamp	03 SEP 2020 12:20
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:14:49

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 ■

FDA-CBER-2022-1614-2893142

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:14:49

	Yes ☐
PC Time stamp	04 SEP 2020 12:10
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

FDA-CBER-2022-1614-2893143

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:14:49

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 ■

FDA-CBER-2022-1614-2893144

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:14:49

	Yes ☐
PC Time stamp	05 SEP 2020 15:19
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

FDA-CBER-2022-1614-2893145

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:14:49

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 ■

FDA-CBER-2022-1614-2893146

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:14:49

	Yes ☐
PC Time stamp	06 SEP 2020 18:05
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

FDA-CBER-2022-1614-2893147

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:14:49

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 ■

FDA-CBER-2022-1614-2893148

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:14:49

	Yes ☐
PC Time stamp	07 SEP 2020 17:21
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

FDA-CBER-2022-1614-2893149

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:14:49

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 ■

FDA-CBER-2022-1614-2893150

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:14:49

	Yes ☐
PC Time stamp	08 SEP 2020 17:33
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

FDA-CBER-2022-1614-2893151

US3642086
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	9 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-2893152

US3642086
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2893153

US3642086
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	17 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-2893154

US3642086
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2893155

US3642086
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	25 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-2893156

US3642086
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2893157

US3642086
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **13 Feb 2021 02:41:31**
Generated On: 10 Jun 2021 09:14:49

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	1 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT2

FDA-CBER-2022-1614-2893158

US3642086
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **13 Feb 2021 02:41:31**
Generated On: 10 Jun 2021 09:14:49

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	01 OCT 2020
Time of assessment *(00:00-23:59)*	13:45 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 13:45
Temperature *(xxx.x)*	98.3 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	75 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	75 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-2893159

US3642086
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **13 Feb 2021 02:41:31**
Generated On: 10 Jun 2021 09:14:49

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	01 OCT 2020
Time of assessment *(00:00-23:59)*	15:55 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 15:55
Temperature *(xxx.x)*	98.3 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	71 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	78 mmHg
Diastolic Blood Pressure units	MMHG

US3642086
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Data signed: (b) (4) **13 Feb 2021 02:41:31**
Generated On: 10 Jun 2021 09:14:49

Was the physical examination performed?	Yes ☑ No ☐
Date of examination *(dd MMM yyyy)*	01 OCT 2020

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

FDA-CBER-2022-1614-2893161

US3642086
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **13 Feb 2021 02:41:31**
Generated On: 10 Jun 2021 09:14:49

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)*	1 OCT 2020
What was the treatment time? *(00:00-23:59)*	15:21 (24 HR)
Treatment Date and Time (derived)	1 OCT 2020 15:21
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

FDA-CBER-2022-1614-2893162

US3642086
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **13 Feb 2021 02:41:31**
Generated On: 10 Jun 2021 09:14:49

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	01 OCT 2020
Collection time *(00:00-23:59)*	14:05 (24 HR)
Collection date and time (derived)	01 OCT 2020 14:05

US3642086
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

Collection date *(dd MMM yyyy)* 01 OCT 2020

Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:09	01 OCT 2020 14:09
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-2893164

US3642086
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **13 Feb 2021 02:41:31**
Generated On: 10 Jun 2021 09:14:49

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2893165

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:14:49

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	01 OCT 2020 15:41
PC Open Date & Time	01 OCT 2020 15:41
PC Close Date & Time	01 OCT 2020 18:11

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.7 °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 OCT 2020 22:26
PC Open Date & Time	01 OCT 2020 19:06
PC Close Date & Time	02 OCT 2020 11:59

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:14:49

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**	98.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	02 OCT 2020 23:07
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

FDA-CBER-2022-1614-2893168

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 3

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.1 °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	03 OCT 2020 14:21
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:14:49

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**	97.8 °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	05 OCT 2020 00:01
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

FDA-CBER-2022-1614-2893170

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 5

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.1 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	05 OCT 2020 13:29
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

FDA-CBER-2022-1614-2893171

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 6

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ☐ No ☐
Please record your **TEMPERATURE in °F**	
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

FDA-CBER-2022-1614-2893172

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:14:49

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**	97.8 °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	07 OCT 2020 13:15
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	01 OCT 2020 15:41
PC Open Date & Time	01 OCT 2020 15:41
PC Close Date & Time	01 OCT 2020 18:11

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	01 OCT 2020 22:26
PC Open Date & Time	01 OCT 2020 19:06
PC Close Date & Time	02 OCT 2020 11:59

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 2
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	02 OCT 2020 23:07
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 3
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	03 OCT 2020 14:21
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

FDA-CBER-2022-1614-2893177

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 4
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	05 OCT 2020 00:01
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

FDA-CBER-2022-1614-2893178

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 5
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	05 OCT 2020 13:30
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 6
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	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 7
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	07 OCT 2020 13:15
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:14:49

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 ☐

FDA-CBER-2022-1614-2893182

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:14:49

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	01 OCT 2020 15:42
PC Open Date & Time	01 OCT 2020 15:41
PC Close Date & Time	01 OCT 2020 18:11

FDA-CBER-2022-1614-2893183

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

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:14:49

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	01 OCT 2020 22:27
PC Open Date & Time	01 OCT 2020 19:06
PC Close Date & Time	02 OCT 2020 11:59

FDA-CBER-2022-1614-2893185

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:14:49

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 ■

FDA-CBER-2022-1614-2893186

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:14:49

	Yes ☐
PC Time stamp	02 OCT 2020 23:08
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

FDA-CBER-2022-1614-2893187

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:14:49

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 ■

FDA-CBER-2022-1614-2893188

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:14:49

	Yes ☐
PC Time stamp	03 OCT 2020 14:22
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

FDA-CBER-2022-1614-2893189

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:14:49

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 ■

FDA-CBER-2022-1614-2893190

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:14:49

	Yes ☐
PC Time stamp	05 OCT 2020 00:01
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

FDA-CBER-2022-1614-2893191

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:14:49

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 ■

FDA-CBER-2022-1614-2893192

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:14:49

	Yes ☐
PC Time stamp	05 OCT 2020 13:30
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

FDA-CBER-2022-1614-2893193

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:14:49

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 ☐

FDA-CBER-2022-1614-2893194

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:14:49

	Yes ☐
PC Time stamp	
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

FDA-CBER-2022-1614-2893195

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:14:49

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 ■

FDA-CBER-2022-1614-2893196

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:14:49

	Yes ☐
PC Time stamp	07 OCT 2020 13:16
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3642086
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	08 OCT 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-2893198

US3642086
Folder: Safety Call Day 36 (1)
Form: Continuing
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2893199

US3642086
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	16 OCT 2020
Please select one status for the follow-up contact	Contact Made ☐ Contact Not Made ■
Comments *If Contact Not Made, please provide Comments*	ATTEMPT 1 15/10/2020 5:00PM ATTEMPT #2 16/10/2020 AT 11:25 AM ATTEMPT #3 16/10/2020 4:19 PM

FDA-CBER-2022-1614-2893200

US3642086
Folder: Safety Call Day 43 (1)
Form: Continuing
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2893201

US3642086
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	26 OCT 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	3 ATTEMPTS MADE UNSUCCESSFUL. SUBJECT CALLED BACK OUT OF WINDOW ON 26OCT2020. ATTEMPT1 23OCT2020 10:07AM ATTEMPT2 23OCT2020 16:00PM ATTEMPT 3 24OCT2020 09:43AM

FDA-CBER-2022-1614-2893202

US3642086
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2893203

US3642086
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **13 Feb 2021 02:41:31**
Generated On: 10 Jun 2021 09:14:49

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	02 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	VISIT3

FDA-CBER-2022-1614-2893204

US3642086
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4) **13 Feb 2021 02:41:31**
Generated On: 10 Jun 2021 09:14:49

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	02 NOV 2020
Time of assessment *(00:00-23:59)*	13:50 (24 HR)
Vital Signs Date and Time (derived)	02 NOV 2020 13:50
Temperature *(xxx.x)*	97.7 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	80 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3642086
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Data signed: (b) (4) **13 Feb 2021 02:41:31**
Generated On: 10 Jun 2021 09:14:49

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.

FDA-CBER-2022-1614-2893206

US3642086
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **13 Feb 2021 02:41:31**
Generated On: 10 Jun 2021 09:14:49

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	02 NOV 2020
Collection time *(00:00-23:59)*	14:05 (24 HR)
Collection date and time (derived)	02 NOV 2020 14:05

US3642086
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **13 Feb 2021 02:41:31**
Generated On: 10 Jun 2021 09:14:49

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2893208

US3642086
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 NOV 2020 16:21:42
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

US3642086
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

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	11 NOV 2020 00:07:51
Patient Cloud Open Date & Time	09 NOV 2020 00:01
Patient Cloud Close Date & Time	13 NOV 2020 23:59

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

FDA-CBER-2022-1614-2893211

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 20:29:49
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

FDA-CBER-2022-1614-2893213

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 NOV 2020 18:01:35
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 DEC 2020 15:36:20
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ■
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	False
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ■
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately
Date and time of submission	20 DEC 2020 15:52:48
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

FDA-CBER-2022-1614-2893220

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

FDA-CBER-2022-1614-2893226

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3642086
Folder: New Safety Follow Up Diary (1)
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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	31 JAN 2021 21:21:57
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

FDA-CBER-2022-1614-2893230

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

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	09 FEB 2021 17:34:30
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

FDA-CBER-2022-1614-2893231

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 FEB 2021 12:41:07
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

FDA-CBER-2022-1614-2893232

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

FDA-CBER-2022-1614-2893233

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3642086
Folder: New Safety Follow Up Diary (1)
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Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 MAR 2021 17:00:58
Patient Cloud Open Date & Time	19 MAR 2021 00:01
Patient Cloud Close Date & Time	23 MAR 2021 23:59

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

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	29 MAR 2021 15:53:58
Patient Cloud Open Date & Time	26 MAR 2021 00:01
Patient Cloud Close Date & Time	30 MAR 2021 23:59

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US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

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	06 APR 2021 13:05:34
Patient Cloud Open Date & Time	02 APR 2021 00:01
Patient Cloud Close Date & Time	06 APR 2021 23:59

FDA-CBER-2022-1614-2893243

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 APR 2021 16:14:05
Patient Cloud Open Date & Time	09 APR 2021 00:01
Patient Cloud Close Date & Time	13 APR 2021 23:59

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 APR 2021 13:58:06
Patient Cloud Open Date & Time	16 APR 2021 00:01
Patient Cloud Close Date & Time	20 APR 2021 23:59

FDA-CBER-2022-1614-2893245

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 APR 2021 17:49:28
Patient Cloud Open Date & Time	23 APR 2021 00:01
Patient Cloud Close Date & Time	27 APR 2021 23:59

FDA-CBER-2022-1614-2893246

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	30 APR 2021 00:01
Patient Cloud Close Date & Time	04 MAY 2021 23:59

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	07 MAY 2021 00:01
Patient Cloud Close Date & Time	11 MAY 2021 23:59

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	14 MAY 2021 00:01
Patient Cloud Close Date & Time	18 MAY 2021 23:59

US3642086
Folder: New Safety Follow Up Diary (1)
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Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	21 MAY 2021 00:01
Patient Cloud Close Date & Time	25 MAY 2021 23:59

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

FDA-CBER-2022-1614-2893255

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	28 MAY 2021 00:01
Patient Cloud Close Date & Time	01 JUN 2021 23:59

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	04 JUN 2021 00:01
Patient Cloud Close Date & Time	08 JUN 2021 23:59

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

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

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	11 JUN 2021 00:01
Patient Cloud Close Date & Time	15 JUN 2021 23:59

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 ≥ 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 ☐

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

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

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 ≥ 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 ☐

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	25 JUN 2021 00:01
Patient Cloud Close Date & Time	29 JUN 2021 23:59

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 ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	02 JUL 2021 00:01
Patient Cloud Close Date & Time	06 JUL 2021 23:59

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 ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	09 JUL 2021 00:01
Patient Cloud Close Date & Time	13 JUL 2021 23:59

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

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

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 ≥ 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 ☐

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

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

FDA-CBER-2022-1614-2893273

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	30 JUL 2021 00:01
Patient Cloud Close Date & Time	03 AUG 2021 23:59

FDA-CBER-2022-1614-2893274

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

FDA-CBER-2022-1614-2893275

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	06 AUG 2021 00:01
Patient Cloud Close Date & Time	10 AUG 2021 23:59

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

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	13 AUG 2021 00:01
Patient Cloud Close Date & Time	17 AUG 2021 23:59

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 ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	20 AUG 2021 00:01
Patient Cloud Close Date & Time	24 AUG 2021 23:59

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 ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	27 AUG 2021 00:01
Patient Cloud Close Date & Time	31 AUG 2021 23:59

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

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 ≥ 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 ☐

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	03 SEP 2021 00:01
Patient Cloud Close Date & Time	07 SEP 2021 23:59

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	10 SEP 2021 00:01
Patient Cloud Close Date & Time	14 SEP 2021 23:59

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 ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	17 SEP 2021 00:01
Patient Cloud Close Date & Time	21 SEP 2021 23:59

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	24 SEP 2021 00:01
Patient Cloud Close Date & Time	28 SEP 2021 23:59

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 ≥ 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 ☐

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

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	08 OCT 2021 00:01
Patient Cloud Close Date & Time	12 OCT 2021 23:59

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 2021 00:01
Patient Cloud Close Date & Time	19 OCT 2021 23:59

FDA-CBER-2022-1614-2893296

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	22 OCT 2021 00:01
Patient Cloud Close Date & Time	26 OCT 2021 23:59

FDA-CBER-2022-1614-2893298

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
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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 ≥ 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 ☐

US3642086
Folder: New Safety Follow Up Diary (1)
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	29 OCT 2021 00:01
Patient Cloud Close Date & Time	02 NOV 2021 23:59

FDA-CBER-2022-1614-2893300

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 ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	05 NOV 2021 00:01
Patient Cloud Close Date & Time	09 NOV 2021 23:59

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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 ≥ 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 ☐

FDA-CBER-2022-1614-2893303

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Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	12 NOV 2021 00:01
Patient Cloud Close Date & Time	16 NOV 2021 23:59

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	19 NOV 2021 00:01
Patient Cloud Close Date & Time	23 NOV 2021 23:59

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TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3642086
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	26 NOV 2021 00:01
Patient Cloud Close Date & Time	30 NOV 2021 23:59

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	03 DEC 2021 00:01
Patient Cloud Close Date & Time	07 DEC 2021 23:59

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	10 DEC 2021 00:01
Patient Cloud Close Date & Time	14 DEC 2021 23:59

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

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

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

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

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TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	31 DEC 2021 00:01
Patient Cloud Close Date & Time	04 JAN 2022 23:59

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 ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	07 JAN 2022 00:01
Patient Cloud Close Date & Time	11 JAN 2022 23:59

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 ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	14 JAN 2022 00:01
Patient Cloud Close Date & Time	18 JAN 2022 23:59

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 ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	21 JAN 2022 00:01
Patient Cloud Close Date & Time	25 JAN 2022 23:59

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	28 JAN 2022 00:01
Patient Cloud Close Date & Time	01 FEB 2022 23:59

FDA-CBER-2022-1614-2893326

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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 ≥ 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 ☐

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	04 FEB 2022 00:01
Patient Cloud Close Date & Time	08 FEB 2022 23:59

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 ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	11 FEB 2022 00:01
Patient Cloud Close Date & Time	15 FEB 2022 23:59

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 ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	18 FEB 2022 00:01
Patient Cloud Close Date & Time	22 FEB 2022 23:59

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 ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	25 FEB 2022 00:01
Patient Cloud Close Date & Time	01 MAR 2022 23:59

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 ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	04 MAR 2022 00:01
Patient Cloud Close Date & Time	08 MAR 2022 23:59

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TIMEPOINT	DAY 558
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	11 MAR 2022 00:01
Patient Cloud Close Date & Time	15 MAR 2022 23:59

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 ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	18 MAR 2022 00:01
Patient Cloud Close Date & Time	22 MAR 2022 23:59

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 ≥ 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 ☐

US3642086
Folder: New Safety Follow Up Diary (1)
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Generated On: 10 Jun 2021 09:14:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	25 MAR 2022 00:01
Patient Cloud Close Date & Time	29 MAR 2022 23:59

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 ≥ 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 ☐

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

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 ≥ 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 ☐

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	08 APR 2022 00:01
Patient Cloud Close Date & Time	12 APR 2022 23:59

FDA-CBER-2022-1614-2893346

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 ≥ 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 ☐

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

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

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	22 APR 2022 00:01
Patient Cloud Close Date & Time	26 APR 2022 23:59

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

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Generated On: 10 Jun 2021 09:14:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	29 APR 2022 00:01
Patient Cloud Close Date & Time	03 MAY 2022 23:59

FDA-CBER-2022-1614-2893352

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3642086
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Generated On: 10 Jun 2021 09:14:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	06 MAY 2022 00:01
Patient Cloud Close Date & Time	10 MAY 2022 23:59

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TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

FDA-CBER-2022-1614-2893355

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Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	13 MAY 2022 00:01
Patient Cloud Close Date & Time	17 MAY 2022 23:59

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	20 MAY 2022 00:01
Patient Cloud Close Date & Time	24 MAY 2022 23:59

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

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Generated On: 10 Jun 2021 09:14:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	27 MAY 2022 00:01
Patient Cloud Close Date & Time	31 MAY 2022 23:59

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 ≥ 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 ☐

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	03 JUN 2022 00:01
Patient Cloud Close Date & Time	07 JUN 2022 23:59

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	10 JUN 2022 00:01
Patient Cloud Close Date & Time	14 JUN 2022 23:59

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 ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	17 JUN 2022 00:01
Patient Cloud Close Date & Time	21 JUN 2022 23:59

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 ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	24 JUN 2022 00:01
Patient Cloud Close Date & Time	28 JUN 2022 23:59

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	01 JUL 2022 00:01
Patient Cloud Close Date & Time	05 JUL 2022 23:59

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 ≥ 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 ☐

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

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

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Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2022 00:01
Patient Cloud Close Date & Time	19 JUL 2022 23:59

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

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

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	29 JUL 2022 00:01
Patient Cloud Close Date & Time	02 AUG 2022 23:59

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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 ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	05 AUG 2022 00:01
Patient Cloud Close Date & Time	09 AUG 2022 23:59

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 ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	12 AUG 2022 00:01
Patient Cloud Close Date & Time	16 AUG 2022 23:59

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 ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	19 AUG 2022 00:01
Patient Cloud Close Date & Time	23 AUG 2022 23:59

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 ≥ 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 ☐

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	26 AUG 2022 00:01
Patient Cloud Close Date & Time	30 AUG 2022 23:59

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	02 SEP 2022 00:01
Patient Cloud Close Date & Time	06 SEP 2022 23:59

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	09 SEP 2022 00:01
Patient Cloud Close Date & Time	13 SEP 2022 23:59

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 ≥ 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 ☐

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	16 SEP 2022 00:01
Patient Cloud Close Date & Time	20 SEP 2022 23:59

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

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

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	30 SEP 2022 00:01
Patient Cloud Close Date & Time	04 OCT 2022 23:59

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 ≥ 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 ☐

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	07 OCT 2022 00:01
Patient Cloud Close Date & Time	11 OCT 2022 23:59

FDA-CBER-2022-1614-2893398

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 ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2022 00:01
Patient Cloud Close Date & Time	18 OCT 2022 23:59

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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 ≥ 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 ☐

US3642086
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	21 OCT 2022 00:01
Patient Cloud Close Date & Time	25 OCT 2022 23:59

FDA-CBER-2022-1614-2893402

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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 ≥ 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 ☐

FDA-CBER-2022-1614-2893403

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	28 OCT 2022 00:01
Patient Cloud Close Date & Time	01 NOV 2022 23:59

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49

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 ≥ 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 ☐

FDA-CBER-2022-1614-2893405

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 NOV 2022 00:01
Patient Cloud Close Date & Time	08 NOV 2022 23:59

US3642086
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary
Generated On: 10 Jun 2021 09:14:49

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		03 MAR 2021 17:17:49

FDA-CBER-2022-1614-2893407

US3642086
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	28 NOV 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-2893408

US3642086
Folder: Safety Call Day 85 (1)
Form: Continuing
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2893409

US3642086
Folder: Safety Call Day 119 (1)
Form: Safety Call
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	29 DEC 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-2893410

US3642086
Folder: Safety Call Day 119 (1)
Form: Continuing
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2893411

US3642086
Folder: Safety Call Day 149 (1)
Form: Safety Call
Data signed: (b) (4) **26 Mar 2021 21:17:34**
Generated On: 10 Jun 2021 09:14:49

Was Contact Attempted?	Yes ☑ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	29 JAN 2021
Please select one status for the follow-up contact	Contact Made ☐ Contact Not Made ☑
Comments *If Contact Not Made, please provide Comments*	UNABLE TO REACH PT AFTER MULTIPLE ATTEMPTS ON 1/29/21, 2/1/21, 2/2/21, EMAIL SENT.

FDA-CBER-2022-1614-2893412

US3642086
Folder: Safety Call Day 149 (1)
Form: Continuing
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2893413

US3642086
Folder: Safety Call Day 179 (1)
Form: Safety Call
Data signed: (b) (4) **06 Mar 2021 01:41:13**
Generated On: 10 Jun 2021 09:14:49

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	03 MAR 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-2893414

US3642086
Folder: Safety Call Day 179 (1)
Form: Continuing
Data signed: (b) (4) **06 Mar 2021 01:41:13**
Generated On: 10 Jun 2021 09:14:49

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2893415

US3642086
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Data signed: (b) (4) **03 Apr 2021 23:28:27**
Generated On: 10 Jun 2021 09:14:49

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	25 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	VISIT4

FDA-CBER-2022-1614-2893416

US3642086
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Data signed: (b) (4) **03 Apr 2021 23:28:27**
Generated On: 10 Jun 2021 09:14:49

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)	

US3642086
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Data signed: (b) (4) **03 Apr 2021 23:28:27**
Generated On: 10 Jun 2021 09:14:49

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.

FDA-CBER-2022-1614-2893418

US3642086
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **03 Apr 2021 23:28:27**
Generated On: 10 Jun 2021 09:14:49

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	25 MAR 2021
Collection time *(00:00-23:59)*	15:21 (24 HR)
Collection date and time (derived)	25 MAR 2021 15:21

FDA-CBER-2022-1614-2893419

US3642086
Folder: Visit 4 Day 209 (1)
Form: Continuing
Data signed: (b) (4) **03 Apr 2021 23:28:27**
Generated On: 10 Jun 2021 09:14:49

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2893420

US3642086
Folder: Safety Call Day 239 (1)
Form: Safety Call
Data signed: (b) (4) **28 Apr 2021 23:40:00**
Generated On: 10 Jun 2021 09:14:49

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	28 APR 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-2893421

US3642086
Folder: Safety Call Day 239 (1)
Form: Continuing
Data signed: (b) (4) **28 Apr 2021 23:40:00**
Generated On: 10 Jun 2021 09:14:49

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2893422

US3642086
Folder: Safety Call Day 269 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49

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	

FDA-CBER-2022-1614-2893423

Is the participant continuing to the next visit?	Yes ☐ No ☐
Continuing Flag	

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: COVID-19 Contact
Data signed: (b) (4) **13 Feb 2021 02:41:25**
Generated On: 10 Jun 2021 09:14:49

Date of Contact	22 DEC 2020
Time of Contact	10:30
Date and Time of Contact (derived)	22 DEC 2020 10:30
Type of Contact	Clinic Visit - Scheduled ☐ Clinical Visit - Unscheduled ■ Safety Call ☐ Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ■ No ☐

FDA-CBER-2022-1614-2893425

Symptom Day

- [x] Day 1
- [ ] Day 2
- [ ] Day 3
- [ ] Day 4
- [ ] Day 5
- [ ] Day 6
- [ ] Day 7
- [ ] Day 8
- [ ] Day 9
- [ ] Day 10
- [ ] Day 11
- [ ] Day 12
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- [ ] Day 14
- [ ] Day 15
- [ ] Day 16
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- [ ] Day 30
- [ ] Day 31
- [ ] Day 32

FDA-CBER-2022-1614-2893426

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	18 DEC 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	ND - Not Done
Chills	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (1)
Data signed: (b) (4) **13 Feb 2021 02:41:25**
Generated On: 10 Jun 2021 09:14:49

	Not Done ☐
Fatigue	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Muscle Aches (Myalgia)	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Body Aches	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Headache	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Taste	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Smell	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐

FDA-CBER-2022-1614-2893428

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

Symptom Day

- [ ] Day 1
- [x] Day 2
- [ ] Day 3
- [ ] Day 4
- [ ] Day 5
- [ ] Day 6
- [ ] Day 7
- [ ] Day 8
- [ ] Day 9
- [ ] Day 10
- [ ] Day 11
- [ ] Day 12
- [ ] Day 13
- [ ] Day 14
- [ ] Day 15
- [ ] Day 16
- [ ] Day 17
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- [ ] Day 30
- [ ] Day 31
- [ ] Day 32

FDA-CBER-2022-1614-2893430

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	19 DEC 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	99.1 F
Chills	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (2)
Data signed: (b) (4) **13 Feb 2021 02:41:25**
Generated On: 10 Jun 2021 09:14:49

	Not Done ☐
Fatigue	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Muscle Aches (Myalgia)	None ☐
	Mild ☐
	Moderate ☐
	Severe ■
	Not Done ☐
Body Aches	None ☐
	Mild ☐
	Moderate ☐
	Severe ■
	Not Done ☐
Headache	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Taste	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Smell	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

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

Symptom Day

- [ ] Day 1
- [ ] Day 2
- [x] Day 3
- [ ] Day 4
- [ ] Day 5
- [ ] Day 6
- [ ] Day 7
- [ ] Day 8
- [ ] Day 9
- [ ] Day 10
- [ ] Day 11
- [ ] Day 12
- [ ] Day 13
- [ ] Day 14
- [ ] Day 15
- [ ] Day 16
- [ ] Day 17
- [ ] Day 18
- [ ] Day 19
- [ ] Day 20
- [ ] Day 21
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- [ ] Day 30
- [ ] Day 31
- [ ] Day 32

FDA-CBER-2022-1614-2893434

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	20 DEC 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	97 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (3)
Data signed: (b) (4) **13 Feb 2021 02:41:25**
Generated On: 10 Jun 2021 09:14:49

	Not Done ☐
Fatigue	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
Muscle Aches (Myalgia)	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Body Aches	None ☐
	Mild ☐
	Moderate ☐
	Severe ■
	Not Done ☐
Headache	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Taste	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Smell	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

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

Symptom Day

- [ ] Day 1
- [ ] Day 2
- [ ] Day 3
- [x] Day 4
- [ ] Day 5
- [ ] Day 6
- [ ] Day 7
- [ ] Day 8
- [ ] Day 9
- [ ] Day 10
- [ ] Day 11
- [ ] Day 12
- [ ] Day 13
- [ ] Day 14
- [ ] Day 15
- [ ] Day 16
- [ ] Day 17
- [ ] Day 18
- [ ] Day 19
- [ ] Day 20
- [ ] Day 21
- [ ] Day 22
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- [ ] Day 28
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- [ ] Day 30
- [ ] Day 31
- [ ] Day 32

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	21 DEC 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	98 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (4)
Data signed: (b) (4) **13 Feb 2021 02:41:25**
Generated On: 10 Jun 2021 09:14:49

	Not Done ☐
Fatigue	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
Muscle Aches (Myalgia)	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Body Aches	None ☐
	Mild ☐
	Moderate ☐
	Severe ■
	Not Done ☐
Headache	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Taste	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Smell	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

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

FDA-CBER-2022-1614-2893441

Symptom Day

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

FDA-CBER-2022-1614-2893442

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	22 DEC 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	98.5 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (5)
Data signed: (b) (4) **13 Feb 2021 02:41:25**
Generated On: 10 Jun 2021 09:14:49

	Not Done ☐
Fatigue	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
Muscle Aches (Myalgia)	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Body Aches	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
Headache	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Taste	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Smell	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

FDA-CBER-2022-1614-2893444

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

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
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- Day 22
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- Day 25
- Day 26
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- Day 28
- Day 29
- Day 30
- Day 31
- Day 32

FDA-CBER-2022-1614-2893446

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	23 DEC 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	99.9 F
Chills	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (6)
Data signed: (b) (4) **13 Feb 2021 02:41:25**
Generated On: 10 Jun 2021 09:14:49

	Not Done ☐
Fatigue	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
Muscle Aches (Myalgia)	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
Body Aches	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
Headache	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Taste	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Smell	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

FDA-CBER-2022-1614-2893448

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

FDA-CBER-2022-1614-2893449

Symptom Day

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

FDA-CBER-2022-1614-2893450

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	24 DEC 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	100 F
Chills	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (7)
Data signed: (b) (4) **13 Feb 2021 02:41:25**
Generated On: 10 Jun 2021 09:14:49

	Not Done ☐
Fatigue	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
Muscle Aches (Myalgia)	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
Body Aches	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
Headache	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Taste	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Smell	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

FDA-CBER-2022-1614-2893452

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

Symptom Day

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

FDA-CBER-2022-1614-2893454

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	25 DEC 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	100.8 F
Chills	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (8)
Data signed: (b) (4) **13 Feb 2021 02:41:25**
Generated On: 10 Jun 2021 09:14:49

	Not Done ☐
Fatigue	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
Muscle Aches (Myalgia)	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
Body Aches	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
Headache	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Taste	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Smell	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

FDA-CBER-2022-1614-2893456

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

FDA-CBER-2022-1614-2893457

Symptom Day

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

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	26 DEC 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	100.7 F
Chills	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (9)
Data signed: (b) (4) **13 Feb 2021 02:41:25**
Generated On: 10 Jun 2021 09:14:49

	Not Done ☐
Fatigue	None ☐ Mild ☐ Moderate ■ Severe ☐ Not Done ☐
Muscle Aches (Myalgia)	None ☐ Mild ☐ Moderate ■ Severe ☐ Not Done ☐
Body Aches	None ☐ Mild ☐ Moderate ■ Severe ☐ Not Done ☐
Headache	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Taste	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Smell	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐

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

Symptom Day

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

FDA-CBER-2022-1614-2893462

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	27 DEC 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	100 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (10)
Data signed: (b) (4) **13 Feb 2021 02:41:25**
Generated On: 10 Jun 2021 09:14:49

	Not Done ☐
Fatigue	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
Muscle Aches (Myalgia)	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Body Aches	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
Headache	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Taste	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Smell	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

FDA-CBER-2022-1614-2893464

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

Symptom Day

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

FDA-CBER-2022-1614-2893466

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	28 DEC 2020
Assessment Not Done	False
O2 Saturation	97 %
O2 Saturation Units	%
Temperature	100.7 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ☐ Moderate ■ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (11)
Data signed: (b) (4) **13 Feb 2021 02:41:25**
Generated On: 10 Jun 2021 09:14:49

	Not Done ☐
Fatigue	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Muscle Aches (Myalgia)	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Body Aches	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
Headache	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Taste	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Smell	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

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

Symptom Day

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

FDA-CBER-2022-1614-2893470

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	29 DEC 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	100.2 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ☐ Moderate ■ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (12)
Data signed: (b) (4) **13 Feb 2021 02:41:25**
Generated On: 10 Jun 2021 09:14:49

	Not Done ☐
Fatigue	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Muscle Aches (Myalgia)	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Body Aches	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Headache	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
New Loss of Taste	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Smell	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

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

FDA-CBER-2022-1614-2893473

Symptom Day

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

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	30 DEC 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	98 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ☐ Moderate ☐ Severe ■ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (13)
Data signed: (b) (4) **13 Feb 2021 02:41:25**
Generated On: 10 Jun 2021 09:14:49

	Not Done ☐
Fatigue	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Muscle Aches (Myalgia)	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Body Aches	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Headache	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Taste	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Smell	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

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

Symptom Day

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

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	31 DEC 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	98.8 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ☐ Moderate ■ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (14)
Data signed: (b) (4) **13 Feb 2021 02:41:25**
Generated On: 10 Jun 2021 09:14:49

	Not Done ☐
Fatigue	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Muscle Aches (Myalgia)	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Body Aches	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Headache	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Taste	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Smell	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

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

Symptom Day

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

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	01 JAN 2021
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	98.8 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ☐ Moderate ■ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (15)
Data signed: (b) (4) **13 Feb 2021 02:41:25**
Generated On: 10 Jun 2021 09:14:49

	Not Done ☐
Fatigue	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Muscle Aches (Myalgia)	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Body Aches	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Headache	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
New Loss of Taste	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Smell	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

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

FDA-CBER-2022-1614-2893485

Symptom Day

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

FDA-CBER-2022-1614-2893486

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	02 JAN 2021
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	98 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (16)
Data signed: (b) (4) **13 Feb 2021 02:41:25**
Generated On: 10 Jun 2021 09:14:49

	Not Done ☐
Fatigue	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Muscle Aches (Myalgia)	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Body Aches	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Headache	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Taste	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Smell	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐

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

Symptom Day

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

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	03 JAN 2021
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	98 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (17)
Data signed: (b) (4) **13 Feb 2021 02:41:25**
Generated On: 10 Jun 2021 09:14:49

	Not Done ☐
Fatigue	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Muscle Aches (Myalgia)	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Body Aches	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Headache	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Taste	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Smell	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐

FDA-CBER-2022-1614-2893492

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

Symptom Day

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

FDA-CBER-2022-1614-2893494

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	4 JAN 2021
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	98.4 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

	Not Done ☐
Fatigue	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Muscle Aches (Myalgia)	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Body Aches	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Headache	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Taste	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Smell	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐

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

Symptom Day

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

FDA-CBER-2022-1614-2893498

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	05 JAN 2021
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	98 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (19)
Data signed: (b) (4) **13 Feb 2021 02:41:25**
Generated On: 10 Jun 2021 09:14:49

	Not Done ☐
Fatigue	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Muscle Aches (Myalgia)	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Body Aches	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Headache	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Taste	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Smell	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

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

Symptom Day

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

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	06 JAN 2021
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	98 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

	Not Done ☐
Fatigue	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Muscle Aches (Myalgia)	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Body Aches	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Headache	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Taste	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Smell	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐

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

FDA-CBER-2022-1614-2893505

Symptom Day

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

FDA-CBER-2022-1614-2893506

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	07 JAN 2021
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	98 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (21)
Data signed: (b) (4) **13 Feb 2021 02:41:25**
Generated On: 10 Jun 2021 09:14:49

	Not Done ☐
Fatigue	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Muscle Aches (Myalgia)	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Body Aches	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Headache	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Taste	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Smell	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐

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

Symptom Day

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

FDA-CBER-2022-1614-2893510

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	08 JAN 2021
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	98 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (22)
Data signed: (b) (4) **13 Feb 2021 02:41:25**
Generated On: 10 Jun 2021 09:14:49

	Not Done ☐
Fatigue	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Muscle Aches (Myalgia)	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Body Aches	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Headache	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Taste	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Smell	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

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

Symptom Day

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

FDA-CBER-2022-1614-2893514

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	09 JAN 2021
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	98.2 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (23)
Data signed: (b) (4) **13 Feb 2021 02:41:25**
Generated On: 10 Jun 2021 09:14:49

	Not Done ☐
Fatigue	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Muscle Aches (Myalgia)	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Body Aches	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Headache	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Taste	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Smell	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐

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

Symptom Day

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

FDA-CBER-2022-1614-2893518

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	10 JAN 2021
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	98 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

	Not Done ☐
Fatigue	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Muscle Aches (Myalgia)	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Body Aches	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Headache	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Taste	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Smell	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐

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

FDA-CBER-2022-1614-2893521

Symptom Day

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

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	11 JAN 2021
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	98 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (25)
Data signed: (b) (4) **13 Feb 2021 02:41:25**
Generated On: 10 Jun 2021 09:14:49

	Not Done ☐
Fatigue	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Muscle Aches (Myalgia)	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Body Aches	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Headache	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Taste	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Smell	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐

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

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: COVID Diagnostic Test
Data signed: (b) (4) **13 Feb 2021 02:41:25**
Generated On: 10 Jun 2021 09:14:49

Date of Visit	22 DEC 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes ■ No ☐
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes ■ No ☐
Date of Test	22 DEC 2020
Type of Test Performed	Nasopharyngeal Swab ■ Nasal Swab ☐ Saliva Test ☐ Other ☐
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ☐ No ■
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes ☐ No ☐
COVID-19 Positive (CSA Programming Field Only)	1

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Did the subject have Respiratory Rates ≥ 30 per Minute?	Yes ☐ No ■
If Yes, provide:	
Start Date	
End Date	
Respiratory Rate	
Did the subject have Heart Rate ≥ 125 beats per minute	Yes ☐ No ■
If Yes, provide:	
Start Date	
End Date	
Heart Rate	
Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?	Yes ☐ No ■
If Yes, provide:	
Start Date	
End Date	
Oxygen Saturation	
Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?	Yes ☐ No ■
If Yes, provide:	
Start Date	
End Date	
PaO2	

Did the subject have Respiratory failure?	Yes ☐ No ■
Start Date	
Did the subject have Acute Respiratory Distress Syndrome (ARDS)?	Yes ☐ No ■
Start Date	

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

Ventilator Support:	
High-Flow Oxygen?	Yes ☐ No ■
Start Date	
End Date	
Non-Invasive Ventilation?	Yes ☐ No ■
Start Date	
End Date	
Mechanical Ventilation?	Yes ☐ No ■
Start Date	
End Date	
ECMO?	Yes ☐ No ■
Start Date	
End Date	
Evidence of Shock:	
Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg	Yes ☐ No ■
Start Date	
End Date	
Evidence of Shock Requires Vasopressors	Yes ☐ No ■
Start Date	
End Date	
Acute Renal Dysfunction?	Yes ☐ No ■
Start Date	

Hepatic Dysfunction?	Yes ☐ No ■
Start Date	
Neurologic Dysfunction?	Yes ☐ No ■
Start Date	

Evidence of Pneumonia:

Clinical Evidence	Yes ☐ No ■
Date of Assessment	
Radiographical Evidence	Yes ☐ No ■
Date of Assessment	

Admission to an intensive care unit due to SARS-CoV-2	Yes ☐ No ■
Start Date	
End Date	

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Generate Next COVID-19 Assessment
Data signed: (b) (4) **13 Feb 2021 02:41:25**
Generated On: 10 Jun 2021 09:14:49

Generate Next COVID-19 Assessment	Yes ☐ No ■

FDA-CBER-2022-1614-2893530

US3642086
Folder: Illness Visit (1)
Form: Saliva Collection
Data signed: (b) (4) **06 Mar 2021 01:41:13**
Generated On: 10 Jun 2021 09:14:49

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	24 DEC 2020
Day 5	Yes	26 DEC 2020
Day 7	Yes	28 DEC 2020
Day 9	Yes	30 DEC 2020
Day 14	Yes	04 JAN 2021
Day 21	Yes	11 JAN 2021
Day 28	Yes	20 JAN 2021

US3642086
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Data signed: (b) (4) **13 Feb 2021 02:41:27**
Generated On: 10 Jun 2021 09:14:49

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	22 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SICKD1

FDA-CBER-2022-1614-2893532

US3642086
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Data signed: (b) (4) **13 Feb 2021 02:41:27**
Generated On: 10 Jun 2021 09:14:49

Were vital signs assessed?	Yes ● No ○
Date of assessment *(dd MMM yyyy)*	22 DEC 2020
Time of assessment *(00:00-23:59)*	10:37 (24 HR)
Vital Signs Date and Time (derived)	22 DEC 2020 10:37
Height *(xxx.x)*	ND - Not Done
Weight *(xxx.x)*	ND - Not Done
Temperature *(xxx.x)*	98.5 F
Route of measurement	Oral ● Axillary ○ Other ○
If Other, specify	
Pulse *(xxx)*	78 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
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)	

US3642086
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Data signed: (b) (4) **13 Feb 2021 02:41:27**
Generated On: 10 Jun 2021 09:14:49

Was the physical examination performed?	Yes ☑ No ☐
Date of examination *(dd MMM yyyy)*	22 DEC 2020

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

FDA-CBER-2022-1614-2893534

US3642086
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Data signed: (b) (4) **13 Feb 2021 02:41:27**
Generated On: 10 Jun 2021 09:14:49

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ■ No ☐ NA (COVID-19 Negative) ☐
Date of Collection	22 DEC 2020

FDA-CBER-2022-1614-2893535

US3642086
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Data signed: (b) (4) **13 Feb 2021 02:41:25**
Generated On: 10 Jun 2021 09:14:49

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	20 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SICKD28

FDA-CBER-2022-1614-2893536

US3642086
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Data signed: (b) (4) **13 Feb 2021 02:41:25**
Generated On: 10 Jun 2021 09:14:49

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	20 JAN 2021
Time of assessment *(00:00-23:59)*	14:20 (24 HR)
Vital Signs Date and Time (derived)	20 JAN 2021 14:20
Height *(xxx.x)*	ND - Not Done
Weight *(xxx.x)*	ND - Not Done
Temperature *(xxx.x)*	98.3 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	81 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3642086
Folder: Convalescence Visit Day 28 (1)
Form: Physical Examination
Data signed: (b) (4) **13 Feb 2021 02:41:25**
Generated On: 10 Jun 2021 09:14:49

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	20 JAN 2021

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

US3642086
Folder: Convalescence Visit Day 28 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Data signed: (b) (4) **13 Feb 2021 02:41:25**
Generated On: 10 Jun 2021 09:14:49

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ■ No ☐ NA (COVID-19 Negative) ☐
Date of Collection	20 JAN 2021

FDA-CBER-2022-1614-2893539

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	20 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	UNBLND_DECIDE

FDA-CBER-2022-1614-2893540

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Data signed: (b) (4) **13 Mar 2021 02:13:36**
Generated On: 10 Jun 2021 09:14:49

Date of updated informed consent *(dd MMM yyyy)*	20 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ■ No ☐
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ☐ Amendment 6 or later ■
Date of unblinding *(dd MMM yyyy)*	08 JAN 2021
Participant randomization assignment	mRNA-1273 ☐ Placebo ■
Actual Dose 1	mRNA-1273 ☐ Placebo ■ Not Administered ☐
Actual Dose 2	mRNA-1273 ☐ Placebo ■ Not Administered ☐
Will participant receive mRNA-1273?	Yes ■ No ☐
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

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

FDA-CBER-2022-1614-2893542

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	20 JAN 2021
Time of assessment *(00:00-23:59)*	14:20 (24 HR)
Vital Signs Date and Time (derived)	20 JAN 2021 14:20
Temperature *(xxx.x)*	98.3 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	81 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	72 mmHg
Diastolic Blood Pressure units	MMHG

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	20 JAN 2021
Time of assessment *(00:00-23:59)*	16:08 (24 HR)
Vital Signs Date and Time (derived)	20 JAN 2021 16:08
Temperature *(xxx.x)*	98 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	76 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	75 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-2893544

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Physical Examination
Data signed: (b) (4) **19 Apr 2021 18:02:04**
Generated On: 10 Jun 2021 09:14:49

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	20 JAN 2021

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

FDA-CBER-2022-1614-2893545

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

Was study treatment given?	Yes ■ No ☐
If No, reason not given	Participant declined due to Adverse Event ☐ Physician withheld dose due to Adverse Event ☐ Death ☐ Lost To Follow-Up ☐ Physician Decision ☐ Pregnancy ☐ Protocol Deviation ☐ Study Terminated by Sponsor ☐ Withdrawal of Consent by Participant ☐ Confirmed COVID-19 ☐ Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	20 JAN 2021
What was the treatment time? *(00:00-23:59)*	15:25 (24 HR)
Treatment Date and Time (derived)	20 JAN 2021 15:25
Which arm was used to give treatment?	Left Arm ■ Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	20 JAN 2021
Collection time *(00:00-23:59)*	15:10 (24 HR)
Collection date and time (derived)	20 JAN 2021 15:10

FDA-CBER-2022-1614-2893547

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Data signed: (b) (4) **13 Feb 2021 02:41:27**
Generated On: 10 Jun 2021 09:14:49

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	20 JAN 2021
Collection time *(00:00 - 23:59)*	15:07
Collection Date and Time (derived)	20 JAN 2021 15:07

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Continuing
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

Is the participant continuing to the next visit?	Yes ☑ No ☐
Continuing Flag	1

US3642086
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Data signed: (b) (4) **26 Mar 2021 21:17:34**
Generated On: 10 Jun 2021 09:14:49

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	27 JAN 2021
Please select one status for the follow-up contact	Contact Made ☐ Contact Not Made ■
Comments *If Contact Not Made, please provide Comments*	UNABLE TO REACH PT AFTER MULTIPLE ATTEMPTS ON 1/27/21, 1/28/21, 1/28/21, EMAIL. SENT.

FDA-CBER-2022-1614-2893550

US3642086
Folder: Safety Call OL-D8 (1)
Form: Continuing
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1
OLD29 Placebo Flag	1

FDA-CBER-2022-1614-2893551

US3642086
Folder: OL-D29 (1)
Form: Visit Date
Data signed: (b) (4) **06 Mar 2021 01:41:13**
Generated On: 10 Jun 2021 09:14:49

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	24 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	OLD29

FDA-CBER-2022-1614-2893552

US3642086
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **06 Mar 2021 01:41:13**
Generated On: 10 Jun 2021 09:14:49

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	24 FEB 2021
Time of assessment *(00:00-23:59)*	13:16 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 13:16
Temperature *(xxx.x)*	98.7 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	70 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	72 mmHg
Diastolic Blood Pressure units	MMHG

US3642086
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **06 Mar 2021 01:41:13**
Generated On: 10 Jun 2021 09:14:49

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	24 FEB 2021
Time of assessment *(00:00-23:59)*	14:50 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 14:50
Temperature *(xxx.x)*	98.4 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	70 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	75 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-2893554

US3642086
Folder: OL-D29 (1)
Form: Physical Examination
Data signed: (b) (4) **06 Mar 2021 01:41:13**
Generated On: 10 Jun 2021 09:14:49

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.

US3642086
Folder: OL-D29 (1)
Form: Exposure
Data signed: (b) (4) **06 Mar 2021 01:41:13**
Generated On: 10 Jun 2021 09:14:49

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)*	24 FEB 2021
What was the treatment time? *(00:00-23:59)*	14:12 (24 HR)
Treatment Date and Time (derived)	24 FEB 2021 14:12
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

FDA-CBER-2022-1614-2893556

US3642086
Folder: OL-D29 (1)
Form: Continuing
Data signed: (b) (4) **06 Mar 2021 01:41:13**
Generated On: 10 Jun 2021 09:14:49

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2893557

US3642086
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Data signed: (b) (4) **06 Mar 2021 01:41:13**
Generated On: 10 Jun 2021 09:14:49

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	04 MAR 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-2893558

US3642086
Folder: Safety Call OL-D36 (1)
Form: Continuing
Data signed: (b) (4) **06 Mar 2021 01:41:13**
Generated On: 10 Jun 2021 09:14:49

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2893559

US3642086
Folder: OL-D57 (1)
Form: Visit Date
Data signed: (b) (4) **03 Apr 2021 23:28:27**
Generated On: 10 Jun 2021 09:14:49

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	25 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	OLD57

FDA-CBER-2022-1614-2893560

US3642086
Folder: OL-D57 (1)
Form: Vital Signs
Data signed: (b) (4) **03 Apr 2021 23:28:27**
Generated On: 10 Jun 2021 09:14:49

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)	

US3642086
Folder: OL-D57 (1)
Form: Physical Examination
Data signed: (b) (4) **03 Apr 2021 23:28:27**
Generated On: 10 Jun 2021 09:14:49

Was the physical examination performed?	Yes ☐ No ■
Date of examination *(dd MMM yyyy)*	

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

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US3642086
Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **03 Apr 2021 23:28:27**
Generated On: 10 Jun 2021 09:14:49

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	25 MAR 2021
Collection time *(00:00-23:59)*	15:21 (24 HR)
Collection date and time (derived)	25 MAR 2021 15:21

US3642086
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **13 Feb 2021 02:41:24**
Generated On: 10 Jun 2021 09:14:49

Did the participant experience any adverse events?	Yes ■ No ☐

If Yes, enter details on the Adverse Events form.

US3642086
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **28 Apr 2021 23:40:00**
Generated On: 10 Jun 2021 09:14:49

AEID	USA-US109-2020-MRNA-1273-P30 1000010
Adverse event	COVID19
Was this a medically-attended AE?	Yes ■ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ■
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ■ No ☐
Start date *(dd MMM yyyy)*	18 DEC 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	11 JAN 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ■ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ■
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐

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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 ■ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ■ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ■
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ■ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	

Narrative

FDA-CBER-2022-1614-2893566

	SUBJECT REPORTS THAT HE EXPERIENCED COVID19 SYMPTOMS AND WAS TESTED AND TREATED IN THE EMERGENCY DEPARTMENT. HE THEN CAME IN FOR AN ILLNESS VISIT. COVID19 CURRENTLY BEING TREATED WITH PRESCRIBED MEDICATIONS. SUBJECT WILL CONTINUE TO REMAIN ON THE STUDY.
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3642086
Folder: Adverse Events
Form: Adverse Events (3)
Data signed: (b) (4) **28 Apr 2021 23:40:00**
Generated On: 10 Jun 2021 09:14:49

AEID	
Adverse event	UNCONTROLLED TYPE 2 DIABETES
Was this a medically-attended AE?	Yes ■ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ■
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ■
Start date *(dd MMM yyyy)*	03 MAR 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	28 APR 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ■ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ■
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐

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

Narrative

FDA-CBER-2022-1614-2893569

	PATIENT REPORTS THAT HIS PCP ADDED IN A NEW MEDICATION FOR BETTER MANAGEMENT OF HIS TYPE 2 DIABETES. PATIENT CURRENTLY TAKES METFORMIN AND JARDIANCE DAILY. TRULICITY SQ WEEKLY ADDED TO REGIMEN. PATIENT UNABLE TO PROVIDE SPECIFIC LAB VALUES DISCUSSED WITH PROVIDER (HGA1C, GLUCOSE ETC). UNABLE TO ACCESS MEDICAL RECORDS THROUGH CARE EVERYWHERE AS THE PATIENT GETS CARE THROUGH THE VA. MEDICAL RECORDS WILL BE REQUESTED BY STUDY TEAM. CONDITION IS ONGOING AND PATIENT WILL REMAIN ON STUDY. UPDATE: PATIENT REPORTS TODAY THAT HIS TYPE 2 DIABETES IS WELL CONTROLLED AND THAT HIS BLOOD SUGARS ARE WNL AT HOME.
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

FDA-CBER-2022-1614-2893570

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Data signed: (b) (4) **13 Feb 2021 02:41:25**
Generated On: 10 Jun 2021 09:14:49

Were any prior/concomitant medications and/or vaccinations taken?	Yes ■ No ☐

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

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **28 Apr 2021 23:40:00**
Generated On: 10 Jun 2021 09:14:49

Name of Medication	METFORMIN
Prophylaxis	Yes ☐ No ■
Indication	DIABETES TYPE 2
Dose per administration	1000
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ■ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-2893572

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN FEB 2015
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	06 APR 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

Name of Medication	OMEPRAZOLE
Prophylaxis	Yes ☐ No ■
Indication	GASTROESOPHAGEAL REFLUX DISEASE
Dose per administration	20
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ■ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN FEB 2014
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Data signed: (b) (4) **28 Apr 2021 23:40:00**
Generated On: 10 Jun 2021 09:14:49

Name of Medication	TYLENOL
Prophylaxis	Yes ☐ No ■
Indication	HEADACHE
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 ☐

FDA-CBER-2022-1614-2893576

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	02 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	02 OCT 2020
Was this medication taken for solicited event?	Yes ■
	No ☐
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

Name of Medication	FLU VACCINE
Prophylaxis	Yes ■ No ☐
Indication	PROPHYLAXIS FOR FLU
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 ☐

FDA-CBER-2022-1614-2893578

	Intramuscular ■
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	23 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	23 OCT 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

Name of Medication	JARDIANCE
Prophylaxis	Yes ☐ No ■
Indication	DIABETES TYPE II
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 ☐

FDA-CBER-2022-1614-2893580

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	26 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

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

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	18 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	22 OCT 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Data signed: (b) (4) **28 Apr 2021 23:40:00**
Generated On: 10 Jun 2021 09:14:49

Name of Medication	TORADOL
Prophylaxis	Yes ☐ No ■
Indication	BACK PAIN RELATED TO COVID19
Dose per administration	UNK
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ■ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	19 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	19 DEC 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

Name of Medication	TYLENOL WITH CODEINE #3
Prophylaxis	Yes ☐ No ■
Indication	COVID19
Dose per administration	300/30
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ■ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	19 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	22 DEC 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

Name of Medication	NAPROXEN
Prophylaxis	Yes ☐ No ■
Indication	COVID19
Dose per administration	250
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 ☐

FDA-CBER-2022-1614-2893588

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	19 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Data signed: (b) (4) **28 Apr 2021 23:40:00**
Generated On: 10 Jun 2021 09:14:49

Name of Medication	METHOCARBAMOL
Prophylaxis	Yes ☐ No ■
Indication	BODY ACHES RELATED TO COVID19
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	EVERY 4 HOURS AS NEEDED FOR 4 DAYS
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐

FDA-CBER-2022-1614-2893590

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	20 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	24 DEC 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

Name of Medication	TYLENOL
Prophylaxis	Yes ☐ No ■
Indication	FEVERS RELATED TO COVID19
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 ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	24 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	11 JAN 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

Name of Medication	PROMETHAZINE WITH CODEINE
Prophylaxis	Yes ☐ No ■
Indication	NAUSEA WITH COUGH
Dose per administration	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 ☐

FDA-CBER-2022-1614-2893594

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	29 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	11 JAN 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

Name of Medication	ADVAIR (FLUTICASONE 500MCG, SOLUMEDROL 50MCG)
Prophylaxis	Yes ☐ No ■
Indication	COUGH
Dose per administration	500/50
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 ☐

FDA-CBER-2022-1614-2893596

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ■
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	30 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	11 JAN 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

FDA-CBER-2022-1614-2893597

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Data signed: (b) (4) **28 Apr 2021 23:40:00**
Generated On: 10 Jun 2021 09:14:49

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ■
Indication	FEVER, HEADACHE SECONDARY TO COVID 19
Dose per administration	400
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 ☐

FDA-CBER-2022-1614-2893598

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	25 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	11 JAN 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Data signed: (b) (4) **28 Apr 2021 23:40:00**
Generated On: 10 Jun 2021 09:14:49

Name of Medication	ZOFRAN
Prophylaxis	Yes ☐ No ■
Indication	NAUSEA SECONDARY TO COVID19
Dose per administration	4
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ■ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	26 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	26 DEC 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

Name of Medication	MUCINEX
Prophylaxis	Yes ☐ No ■
Indication	CONGESTION SECONDARY TO COVID19
Dose per administration	600
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ■ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	28 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	11 JAN 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Data signed: (b) (4) **28 Apr 2021 23:40:00**
Generated On: 10 Jun 2021 09:14:49

Name of Medication	ASPIRIN
Prophylaxis	Yes ☐ No ■
Indication	FEVER SECONDARY TO COVID19
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 ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	28 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	11 JAN 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

Name of Medication	TRULICITY
Prophylaxis	Yes ☐ No ■
Indication	UNCONTROLLED TYPE 2 DIABETES
Dose per administration	0.75
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ■ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ■ Transdermal ☐

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	03 MAR 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	06 APR 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ■
	804 ☐

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Data signed: (b) (4) **28 Apr 2021 23:40:00**
Generated On: 10 Jun 2021 09:14:49

Name of Medication	TRULICITY
Prophylaxis	Yes ☐ No ■
Indication	DIABETES TYPE 2
Dose per administration	1.5
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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	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	6 APR 2021
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ■
	804 ☐

US3642086
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Data signed: (b) (4) **13 Feb 2021 02:41:25**
Generated On: 10 Jun 2021 09:14:49

Were any concomitant procedures performed?	Yes ☐ No ■

If yes, please complete Concomitant Procedures form.

US3642086
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 10 Jun 2021 09:14:49

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	

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 ☐

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

SAEID	USA-US109-2020-MRNA-1273-P301000010
Serious	Yes ☐ No ■
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ■
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	STEPHEN
Investigator's Last Name	SPECTOR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form (1)
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

SAEID	USA-US109-2020-MRNA-1273-P301000010
Serious	Yes ☐ No ■
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ■
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	STEPHEN
Investigator's Last Name	SPECTOR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	29/DEC/2020 14:55
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

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US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form (2)
Data signed: (b) (4) **13 Feb 2021 02:41:30**
Generated On: 10 Jun 2021 09:14:49

SAEID	USA-US109-2020-MRNA-1273-P301000010
Serious	Yes ☐ No ■
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ■
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	STEPHEN
Investigator's Last Name	SPECTOR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	14/JAN/2021 00:02
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

US3642086 (Prod: University of California San Diego)

US3642086
Form: Participant Creation
Generated On: 10 Jun 2021 09:14:49
Participant ID

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:15:31
User entered 'US3642086'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 22:39:20

US3642086
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:14
User entered 'Yes (Y)'		02 Sep 2020 23:49:30

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US3642086
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:14
User entered '02 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 22:39:21

US3642086
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:14
User entered 'Clinic (Clinic)'		02 Sep 2020 23:49:30

US3642086
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered 'SCRN'	System	02 Sep 2020 23:49:30

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US3642086
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:14:49
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:40:43
User entered (b) (6) 1980'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 22:39:22

US3642086
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:14:49
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:40:43
User entered '40'		02 Sep 2020 23:49:48

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US3642086
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:14:49
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered 'YEARS'	System	02 Sep 2020 23:49:48

US3642086
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:14:49
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered '40'	System	02 Sep 2020 23:50:15

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US3642086
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:14:49
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:40:43
User entered 'Male (M)'		02 Sep 2020 23:49:48

FDA-CBER-2022-1614-2893626

US3642086
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:14:49
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:40:43
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'		02 Sep 2020 23:49:48

US3642086
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:14:49
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:40:43
User entered '1'		02 Sep 2020 23:49:48

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US3642086
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:14:49
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:40:43
User entered '0'		02 Sep 2020 23:49:48

FDA-CBER-2022-1614-2893629

US3642086
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:14:49
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:40:43
User entered '0'		02 Sep 2020 23:49:48

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US3642086
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:14:49
American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:40:43
User entered '0'		02 Sep 2020 23:49:48

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US3642086
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:14:49
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:40:43
User entered '0'		02 Sep 2020 23:49:48

FDA-CBER-2022-1614-2893632

US3642086
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:14:49
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:40:43
User entered '0'		02 Sep 2020 23:49:48

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US3642086
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:14:49
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:40:43
User entered empty.		02 Sep 2020 23:49:48

FDA-CBER-2022-1614-2893634

US3642086
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:14:49
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:40:43
User entered '0'		02 Sep 2020 23:49:48

FDA-CBER-2022-1614-2893635

US3642086
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:14:49
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:40:43
User entered '0'		02 Sep 2020 23:49:48

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US3642086
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:14:49
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
User closed query 'Per CDM: Please complete all forms for this visit ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 03:45:52
Query 'Per CDM: Please complete all forms for this visit ' answered with 'completed' (Site from DM).	Megan Loughran (b) (4)	06 Nov 2020 22:59:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:54:16
User opened query 'Per CDM: Please complete all forms for this visit ' (Site from DM).		23 Sep 2020 11:19:48
User entered '02 Sep 2020'		02 Sep 2020 23:50:15

US3642086
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:14:49
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered 'Sep 2020'	System	02 Sep 2020 23:50:15

US3642086
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:14:49
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered '2020'	System	02 Sep 2020 23:50:15

FDA-CBER-2022-1614-2893639

US3642086
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:14:49
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User closed query 'verify with source, Amendment 3' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 18:54:49
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:54:44
Query 'verify with source, Amendment 3' answered with 'revised' (Site from CRA).	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 22:59:02
User entered 'Amendment 3 (3)' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 22:58:57
User opened query 'verify with source, Amendment 3' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 21:43:20
User entered 'Amendment 1 (1)'		02 Sep 2020 23:50:15

US3642086
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:14:49
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:54:20
User entered 'Yes (Y)'		02 Sep 2020 23:50:15

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US3642086
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:14:49
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:54:22
User entered empty.		02 Sep 2020 23:50:15

FDA-CBER-2022-1614-2893642

US3642086
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:14:49
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:54:24
User entered empty.		02 Sep 2020 23:50:15

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US3642086
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:14:49
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:54:25
User entered 'No (N)'		02 Sep 2020 23:50:15

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US3642086
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:14:49
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:54:27
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 22:39:21

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US3642086
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:14:49
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered '1'	System	02 Sep 2020 23:50:20

US3642086
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 10 Jun 2021 09:14:49
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:44:01
User entered 'Yes (Y)'		02 Sep 2020 23:50:20

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US3642086
Folder: Screening
Form: Medical History Summary
Generated On: 10 Jun 2021 09:14:49
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:44:09
User entered 'Yes (Y)'	Son Do (b) (4)	05 Oct 2020 16:36:46

US3642086
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:14:49
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:56:12
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:39:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:39:33
Data point term sent to Coder	System	05 Oct 2020 16:38:04
User entered 'type 2 diabetes'	Son Do (b) (4)	05 Oct 2020 16:37:08

US3642086
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:14:49
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 21:04:42
User closed query 'Per source screening/D1 visit has start date of 'un-unk-2015'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	29 Jan 2021 21:04:40
Query 'Per source screening/D1 visit has start date of 'un-unk-2015'. Please reconcile. ' answered with 'this information was provided by participant at visit 2, as documented in source. visit 1 source has been updated to reflect the additional information.' (Site from CRA).	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 19:39:12
User opened query 'Per source screening/D1 visit has start date of 'un-unk-2015'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	18 Dec 2020 19:35:31
User closed query 'Per source screening/day 1 visit has start date of 'un-unk-2015', visit 2 has start date of unFeb2017'. Please reconcile. ' (Site from CRA).		18 Dec 2020 19:35:31
Query 'Per source screening/day 1 visit has start date of 'un-unk-2015', visit 2 has start date of unFeb2017'. Please reconcile. ' answered with 'revised' (Site from CRA).	Megan Loughran (b) (4) (b) (4)	24 Nov 2020 18:28:15
User entered 'UN Feb 2015' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	24 Nov 2020 18:28:11
User opened query 'Per source screening/day 1 visit has start date of 'un-unk-2015', visit 2 has start date of unFeb2017'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 18:58:40
User entered 'UN Feb 2017'	Son Do (b) (4)	05 Oct 2020 16:37:08

FDA-CBER-2022-1614-2893650

US3642086
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:14:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:56:14
User entered '0'	Son Do (b) (4)	05 Oct 2020 16:37:08

FDA-CBER-2022-1614-2893651

US3642086
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:14:49
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:56:16
User entered 'Yes (Y)'	Son Do (b) (4)	05 Oct 2020 16:37:08

FDA-CBER-2022-1614-2893652

US3642086
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:14:49
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:56:18
User entered empty.	Son Do (b) (4)	05 Oct 2020 16:37:08

FDA-CBER-2022-1614-2893653

US3642086
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:14:49
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:56:19
User entered '0'	Son Do (b) (4)	05 Oct 2020 16:37:08

FDA-CBER-2022-1614-2893654

US3642086
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:14:49
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered 'Feb 2015'	System	24 Nov 2020 18:28:11
User entered 'Feb 2017'	System	05 Oct 2020 16:37:08

FDA-CBER-2022-1614-2893655

US3642086
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:14:49
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered '2015'	System	24 Nov 2020 18:28:11
User entered '2017'	System	05 Oct 2020 16:37:08

US3642086
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:14:49
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered empty.	System	05 Oct 2020 16:37:08

US3642086
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:14:49
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered empty.	System	05 Oct 2020 16:37:08

US3642086
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:14:49
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:06:37
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: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 18:31:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 18:31:02
Data point term sent to Coder	System	24 Nov 2020 18:29:30
DataPoint Un-verified.	Megan Loughran (b) (4)	24 Nov 2020 18:28:29
Coding entries removed.	Megan Loughran (b) (4)	24 Nov 2020 18:28:29
User entered 'Gastroesophageal reflux disease' reason for change: Data Entry Error	Megan Loughran (b) (4)	24 Nov 2020 18:28:29
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:58:51
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)	05 Oct 2020 16:39:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:39:32
Data point term sent to Coder	System	05 Oct 2020 16:38:05
User entered 'gerd'	Son Do (b) (4)	05 Oct 2020 16:37:23

US3642086
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:14:49
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 21:05:03
User closed query 'Per source screening/D1 visit has start date of 'un-unk-2014'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	29 Jan 2021 21:05:01
Query 'Per source screening/D1 visit has start date of 'un-unk-2014'. Please reconcile. ' answered with 'this information was provided by participant at visit 2, as documented in source. visit 1 source has been updated to reflect the additional information.' (Site from CRA).	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 19:39:20
User opened query 'Per source screening/D1 visit has start date of 'un-unk-2014'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	18 Dec 2020 19:36:20
User closed query 'Per source screening/day 1 visit has start date of 'un-unk-2014', visit 2 has start date of unFeb2017'. Please reconcile.' (Site from CRA).		18 Dec 2020 19:36:20
Query 'Per source screening/day 1 visit has start date of 'un-unk-2014', visit 2 has start date of unFeb2017'. Please reconcile.' answered with 'revised' (Site from CRA).	Megan Loughran (b) (4) (b) (4)	24 Nov 2020 18:28:35
User entered 'UN Feb 2014' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	24 Nov 2020 18:28:29
User opened query 'Per source screening/day 1 visit has start date of 'un-unk-2014', visit 2 has start date of unFeb2017'. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 18:59:44
User entered 'UN Feb 2017'	Son Do (b) (4)	05 Oct 2020 16:37:23

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US3642086
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:14:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:59:47
User entered '0'	Son Do (b) (4)	05 Oct 2020 16:37:23

FDA-CBER-2022-1614-2893661

US3642086
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:14:49
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:59:50
User entered 'Yes (Y)'	Son Do (b) (4)	05 Oct 2020 16:37:23

FDA-CBER-2022-1614-2893662

US3642086
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:14:49
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:59:52
User entered empty.	Son Do (b) (4)	05 Oct 2020 16:37:23

US3642086
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:14:49
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:59:54
User entered '0'	Son Do (b) (4)	05 Oct 2020 16:37:23

FDA-CBER-2022-1614-2893664

US3642086
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:14:49
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered 'Feb 2014'	System	24 Nov 2020 18:28:29
User entered 'Feb 2017'	System	05 Oct 2020 16:37:23

US3642086
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:14:49
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered '2014'	System	24 Nov 2020 18:28:29
User entered '2017'	System	05 Oct 2020 16:37:23

US3642086
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:14:49
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered empty.	System	05 Oct 2020 16:37:23

US3642086
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:14:49
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered empty.	System	05 Oct 2020 16:37:23

FDA-CBER-2022-1614-2893668

US3642086
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:14:49
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:00:15
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 18:29:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 18:29:24
Data point term sent to Coder	System	05 Oct 2020 18:28:01
User entered 'hypercholestrolemia'	Son Do (b) (4)	05 Oct 2020 18:27:31

US3642086
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:14:49
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:00:15
User entered 'UN Aug 2020'	Son Do (b) (4)	05 Oct 2020 18:27:31

FDA-CBER-2022-1614-2893670

US3642086
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:14:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:00:15
User entered '0'	Son Do (b) (4)	05 Oct 2020 18:27:31

FDA-CBER-2022-1614-2893671

US3642086
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:14:49
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:00:15
User entered 'Yes (Y)'	Son Do (b) (4)	05 Oct 2020 18:27:31

FDA-CBER-2022-1614-2893672

US3642086
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:14:49
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:00:15
User entered empty.	Son Do (b) (4)	05 Oct 2020 18:27:31

US3642086
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:14:49
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:00:15
User entered '0'	Son Do (b) (4)	05 Oct 2020 18:27:31

FDA-CBER-2022-1614-2893674

US3642086
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:14:49
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered 'Aug 2020'	System	05 Oct 2020 18:27:31

US3642086
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:14:49
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered '2020'	System	05 Oct 2020 18:27:31

FDA-CBER-2022-1614-2893676

US3642086
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:14:49
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered empty.	System	05 Oct 2020 18:27:31

US3642086
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:14:49
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered empty.	System	05 Oct 2020 18:27:31

FDA-CBER-2022-1614-2893678

US3642086
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:52:33
User entered 'Yes (Y)'	Son Do (b) (4)	04 Nov 2020 16:07:25

US3642086
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:52:33
User entered '02 Sep 2020'	Son Do (b) (4)	04 Nov 2020 16:07:25

US3642086
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:52:33
User entered '15:10'	Son Do (b) (4)	04 Nov 2020 16:07:25

FDA-CBER-2022-1614-2893681

US3642086
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered '02 Sep 2020 15:10'	System	04 Nov 2020 16:07:25

US3642086
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:52:33
User entered '162' cm	Son Do (b) (4)	04 Nov 2020 16:07:25
DataPoint set to visible.	System	02 Sep 2020 23:50:20

FDA-CBER-2022-1614-2893683

US3642086
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:52:33
User entered '85.1' kg	Son Do (b) (4)	04 Nov 2020 16:07:25
DataPoint set to visible.	System	02 Sep 2020 23:50:20

US3642086
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered '32.42646'	System	04 Nov 2020 16:07:25
DataPoint set to visible.	System	02 Sep 2020 23:50:20

US3642086
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered 'kg/m2'	System	04 Nov 2020 16:07:25
DataPoint set to visible.	System	02 Sep 2020 23:50:20

US3642086
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:52:33
User entered missing code ND - Not Done.	Son Do (b) (4)	04 Nov 2020 16:07:25

FDA-CBER-2022-1614-2893687

US3642086
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:52:33
User entered empty.	Son Do (b) (4)	04 Nov 2020 16:07:25

US3642086
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:52:33
User entered empty.	Son Do (b) (4)	04 Nov 2020 16:07:25

FDA-CBER-2022-1614-2893689

US3642086
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:52:33
User entered missing code ND - Not Done.	Son Do (b) (4)	04 Nov 2020 16:07:25

FDA-CBER-2022-1614-2893690

US3642086
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered 'bpm'	System	04 Nov 2020 16:07:25

FDA-CBER-2022-1614-2893691

US3642086
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:52:33
User entered missing code ND - Not Done.	Son Do (b) (4)	04 Nov 2020 16:07:25

US3642086
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered 'breaths/min'	System	04 Nov 2020 16:07:25

FDA-CBER-2022-1614-2893693

US3642086
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:52:33
User entered missing code ND - Not Done.	Son Do (b) (4)	04 Nov 2020 16:07:25

FDA-CBER-2022-1614-2893694

US3642086
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered 'mmHg'	System	04 Nov 2020 16:07:25

FDA-CBER-2022-1614-2893695

US3642086
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:52:33
User entered missing code ND - Not Done.	Son Do (b) (4)	04 Nov 2020 16:07:25

US3642086
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered 'mmHg'	System	04 Nov 2020 16:07:25

FDA-CBER-2022-1614-2893697

US3642086
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15

FDA-CBER-2022-1614-2893698

US3642086
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15

FDA-CBER-2022-1614-2893699

US3642086
Folder: Screening
Form: Physical Examination
Generated On: 10 Jun 2021 09:14:49
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:53:06
User entered 'Yes (Y)'	Son Do (b) (4)	05 Oct 2020 18:28:05

US3642086
Folder: Screening
Form: Physical Examination
Generated On: 10 Jun 2021 09:14:49
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:53:06
User entered '02 Sep 2020'	Son Do (b) (4)	05 Oct 2020 18:28:05

FDA-CBER-2022-1614-2893701

US3642086
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:14:49
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:53:22
User entered 'Yes (Y)'	Son Do (b) (4)	04 Nov 2020 16:11:52

FDA-CBER-2022-1614-2893702

US3642086
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:14:49
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:53:22
User entered 'No (N)'	Son Do (b) (4)	04 Nov 2020 16:11:52

US3642086
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:14:49
Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:53:22
User entered 'No (N)'	Son Do (b) (4)	04 Nov 2020 16:11:52

US3642086
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:14:49
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:53:22
User entered 'No (N)'	Son Do (b) (4)	04 Nov 2020 16:11:52

US3642086
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:14:49
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:53:22
User entered 'No (N)'	Son Do (b) (4)	04 Nov 2020 16:11:52

US3642086
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:14:49
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:53:22
User entered 'No (N)'	Son Do (b) (4)	04 Nov 2020 16:11:52

US3642086
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:14:49
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:53:22
User entered 'No (N)'	Son Do (b) (4)	04 Nov 2020 16:11:52

US3642086
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:14:49
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:53:22
User entered 'No (N)'	Son Do (b) (4)	04 Nov 2020 16:11:52

US3642086
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:14:49
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:53:22
User entered 'No (N)'	Son Do (b) (4)	04 Nov 2020 16:11:52

US3642086
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:14:49
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:53:22
User entered 'No (N)'	Son Do (b) (4)	04 Nov 2020 16:11:52

US3642086
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:14:49
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:53:22
User entered 'No (N)'	Son Do (b) (4)	04 Nov 2020 16:11:52

US3642086
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:14:49
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:53:22
User entered 'No (N)'	Son Do (b) (4)	04 Nov 2020 16:11:52

US3642086
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:14:49
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:53:22
User entered empty.	Son Do (b) (4)	04 Nov 2020 16:11:52

US3642086
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:14:49
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered '0'	Son Do (b) (4)	04 Nov 2020 16:11:52

US3642086
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:14:49
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:53:22
User entered '0'	Son Do (b) (4)	04 Nov 2020 16:11:52

US3642086
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:14:49
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:53:22
User entered '0'	Son Do (b) (4)	04 Nov 2020 16:11:52

US3642086
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:14:49
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:53:22
User entered '0'	Son Do (b) (4)	04 Nov 2020 16:11:52

US3642086
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:14:49
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:53:22
User entered '0'	Son Do (b) (4)	04 Nov 2020 16:11:52

US3642086
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:14:49
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:53:22
User entered '1'	Son Do (b) (4)	04 Nov 2020 16:11:52

US3642086
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:14:49
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered '0'	Son Do (b) (4)	04 Nov 2020 16:11:52

US3642086
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:14:49
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:53:22
User entered empty.	Son Do (b) (4)	04 Nov 2020 16:11:52

US3642086
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:01:18
User closed query 'Per CDM: Please complete all forms for this visit' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 05:54:21
Query 'Per CDM: Please complete all forms for this visit' answered with 'completed' (Site from DM).	Megan Loughran (b) (4)	06 Nov 2020 22:59:41
User opened query 'Per CDM: Please complete all forms for this visit' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 11:20:56
User entered 'Yes (Y)'		02 Sep 2020 23:50:38

US3642086
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 2-Sep-2020 is reported under Visit 1 Day 1 in PPD Central lab; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Nov 2020 13:01:48
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:01:18
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 2-Sep-2020 is reported under Visit 1 Day 1 in PPD Central lab; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify. ' answered with 'data are correct. edc updated' (Site from DM).	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 22:59:51
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 2-Sep-2020 is reported under Visit 1 Day 1 in PPD Central lab; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 11:04:17
User entered '02 Sep 2020'		02 Sep 2020 23:50:38

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US3642086
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:01:18
User entered 'Clinic (Clinic)'		02 Sep 2020 23:50:38

FDA-CBER-2022-1614-2893725

US3642086
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered 'VISIT1'	System	02 Sep 2020 23:50:38

FDA-CBER-2022-1614-2893726

US3642086
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:14:49
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:41
User entered '02 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 22:39:24

FDA-CBER-2022-1614-2893727

US3642086
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:14:49
What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:41
User entered '145359'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 22:39:24

FDA-CBER-2022-1614-2893728

US3642086
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:14:49
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:07:41
User closed query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	06 Nov 2020 23:00:12
Query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' answered by data change (Site from System).	System	06 Nov 2020 23:00:12
Amendment Manager: User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	30 Sep 2020 22:15:30
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	30 Sep 2020 22:15:30
User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	02 Sep 2020 23:50:49
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 22:39:24

US3642086
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:14:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:41
User entered 'No (N)'		02 Sep 2020 23:50:49

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US3642086
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:14:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:41
User entered 'No (N)'		02 Sep 2020 23:50:49

FDA-CBER-2022-1614-2893731

US3642086
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:14:49
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:41
User entered 'No (N)'		02 Sep 2020 23:50:49

FDA-CBER-2022-1614-2893732

US3642086
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:14:49
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 23:00:12
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 23:50:49

US3642086
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:14:49
Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:41
User entered 'No (N)'		02 Sep 2020 23:50:49

FDA-CBER-2022-1614-2893734

US3642086
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:14:49
Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:41
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 23:00:12
DataPoint set to visible.	System	06 Nov 2020 22:58:57
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:03:21

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:14:49
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:08:45
User entered missing code ND - Not Done.	Son Do (b) (4)	04 Nov 2020 16:08:23

FDA-CBER-2022-1614-2893736

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:14:49
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:08:45
User entered missing code ND - Not Done.	Son Do (b) (4)	04 Nov 2020 16:08:23

FDA-CBER-2022-1614-2893737

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:14:49
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:08:45
User entered missing code ND - Not Done.	Son Do (b) (4)	04 Nov 2020 16:08:23

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:14:49
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:08:45
User entered missing code ND - Not Done.	Son Do (b) (4)	04 Nov 2020 16:08:23

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User accepted default value 'Pre-Dose (PREDOSE)'	Son Do (b) (4)	04 Nov 2020 16:08:23

FDA-CBER-2022-1614-2893740

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:08:45
User entered 'Yes (Y)'	Son Do (b) (4)	04 Nov 2020 16:08:23

FDA-CBER-2022-1614-2893741

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:08:45
User entered '02 Sep 2020'	Son Do (b) (4)	04 Nov 2020 16:08:23

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:08:45
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	06 Nov 2020 23:00:49
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	04 Nov 2020 16:08:23
User entered '15:10'	Son Do (b) (4)	04 Nov 2020 16:08:23

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered '02 Sep 2020 15:10'	System	04 Nov 2020 16:08:23

FDA-CBER-2022-1614-2893744

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:08:45
User entered '98.7' F	Son Do (b) (4)	04 Nov 2020 16:08:23

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:06:59
DataPoint Un-verified.	Megan Loughran (b) (4)	29 Jan 2021 19:37:31
User entered 'Other (Other)' reason for change: Data Entry Error	Megan Loughran (b) (4)	29 Jan 2021 19:37:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:08:45
User entered 'Oral (Oral)'	Son Do (b) (4)	04 Nov 2020 16:08:23

FDA-CBER-2022-1614-2893746

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:06:57
DataPoint Un-verified.	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 19:37:31
User entered 'temporal' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 19:37:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:08:45
User entered empty.	Son Do (b) (4)	04 Nov 2020 16:08:23

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:08:45
User entered '80'	Son Do (b) (4)	04 Nov 2020 16:08:23

FDA-CBER-2022-1614-2893748

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered 'bpm'	System	04 Nov 2020 16:08:23

FDA-CBER-2022-1614-2893749

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:08:45
User entered '12'	Son Do (b) (4)	04 Nov 2020 16:08:23

FDA-CBER-2022-1614-2893750

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered 'breaths/min'	System	04 Nov 2020 16:08:23

FDA-CBER-2022-1614-2893751

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:08:45
User entered '131'	Son Do (b) (4)	04 Nov 2020 16:08:23

FDA-CBER-2022-1614-2893752

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered 'mmHg'	System	04 Nov 2020 16:08:23

FDA-CBER-2022-1614-2893753

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:08:45
User entered '90'	Son Do (b) (4)	04 Nov 2020 16:08:23

FDA-CBER-2022-1614-2893754

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered 'mmHg'	System	04 Nov 2020 16:08:23

FDA-CBER-2022-1614-2893755

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:14:49
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:08:45
User entered missing code ND - Not Done.	Son Do (b) (4)	04 Nov 2020 16:08:23

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:14:49
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:08:45
User entered missing code ND - Not Done.	Son Do (b) (4)	04 Nov 2020 16:08:23

FDA-CBER-2022-1614-2893757

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User accepted default value 'Post-Dose (POSTDOSE)'	Son Do (b) (4)	04 Nov 2020 16:08:23

FDA-CBER-2022-1614-2893758

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:08:45
User entered 'Yes (Y)'	Son Do (b) (4)	04 Nov 2020 16:08:23

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:08:45
User entered '02 Sep 2020'	Son Do (b) (4)	04 Nov 2020 16:08:23

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:08:45
User entered '17:11'	Son Do (b) (4)	04 Nov 2020 16:08:23

FDA-CBER-2022-1614-2893761

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered '02 Sep 2020 17:11'	System	04 Nov 2020 16:08:23

FDA-CBER-2022-1614-2893762

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:08:45
User entered '98.5' F	Son Do (b) (4)	04 Nov 2020 16:08:23

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:08:45
User entered 'Oral (Oral)'	Son Do (b) (4)	04 Nov 2020 16:08:23

FDA-CBER-2022-1614-2893764

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:08:45
User entered empty.	Son Do (b) (4)	04 Nov 2020 16:08:23

FDA-CBER-2022-1614-2893765

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:08:45
User entered '73'	Son Do (b) (4)	04 Nov 2020 16:08:23

FDA-CBER-2022-1614-2893766

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered 'bpm'	System	04 Nov 2020 16:08:23

FDA-CBER-2022-1614-2893767

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:08:45
User entered '14'	Son Do (b) (4)	04 Nov 2020 16:08:23

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered 'breaths/min'	System	04 Nov 2020 16:08:23

FDA-CBER-2022-1614-2893769

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:08:45
User entered '126'	Son Do (b) (4)	04 Nov 2020 16:08:23

FDA-CBER-2022-1614-2893770

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered 'mmHg'	System	04 Nov 2020 16:08:23

FDA-CBER-2022-1614-2893771

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:08:45
User entered '70'	Son Do (b) (4)	04 Nov 2020 16:08:23

FDA-CBER-2022-1614-2893772

US3642086
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered 'mmHg'	System	04 Nov 2020 16:08:23

FDA-CBER-2022-1614-2893773

US3642086
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 10 Jun 2021 09:14:49
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 19:32:46
DataPoint Un-verified.	Megan Loughran (b) (4)	24 Nov 2020 18:29:11
User entered 'No (N)' reason for change: Data Entry Error	Megan Loughran (b) (4)	24 Nov 2020 18:29:11
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:08:54
User entered 'Yes (Y)'		02 Sep 2020 23:51:00

FDA-CBER-2022-1614-2893774

US3642086
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 10 Jun 2021 09:14:49
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 19:32:46
DataPoint Un-verified.	Megan Loughran (b) (4) (b) (4)	24 Nov 2020 18:29:11
User entered empty; reason for change Data Entry Error	Megan Loughran (b) (4) (b) (4)	24 Nov 2020 18:29:11
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:08:54
User entered '02 Sep 2020'		02 Sep 2020 23:51:00

FDA-CBER-2022-1614-2893775

US3642086
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
User closed query 'Per GCL Lab Recon: GCL has Visit 1 Day 1 immunogenicity sample with date of 02 SEP 2020 however, sample is not recorded in EDC. Please review and reconcile.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Nov 2020 12:58:47
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:09:13
Query 'Per GCL Lab Recon: GCL has Visit 1 Day 1 immunogenicity sample with date of 02 SEP 2020 however, sample is not recorded in EDC. Please review and reconcile.' answered with 'added to edc' (Site from DM).	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 23:01:01
User opened query 'Per GCL Lab Recon: GCL has Visit 1 Day 1 immunogenicity sample with date of 02 SEP 2020 however, sample is not recorded in EDC. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 14:38:26
User entered 'Yes (Y)'		02 Sep 2020 23:51:18

US3642086
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:09:13
User entered empty.		02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893777

US3642086
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:09:13
User entered empty.		02 Sep 2020 23:51:18

US3642086
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered 'MRNA-1273 OR PLACEBO'	System	02 Sep 2020 23:51:18

US3642086
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:09:13
User entered '02 Sep 2020'		02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893780

US3642086
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:09:13
User entered '16:40' reason for change: Data Entry Error	Megan Loughran (b) (4)	06 Nov 2020 23:00:49
User entered '10:40'	(b) (4), (b) (6)	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893781

US3642086
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered '02 Sep 2020 16:40'	System	06 Nov 2020 23:00:49
User entered '02 Sep 2020 10:40'	System	02 Sep 2020 23:51:18

US3642086
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:09:13
User entered 'Left Arm (LEFT ARM)'		02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893783

US3642086
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
DataPoint Verified.		19 Nov 2020 19:09:13
User entered 'ONCE'	System	02 Sep 2020 23:51:18

US3642086
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered 'INTRAMUSCULAR'	System	02 Sep 2020 23:51:18

US3642086
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:14:49
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:09:25
User entered 'Yes (Y)'	Son Do (b) (4)	04 Nov 2020 16:10:03

FDA-CBER-2022-1614-2893786

US3642086
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:14:49
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:09:25
User entered '02 Sep 2020'	Son Do (b) (4)	04 Nov 2020 16:10:03

US3642086
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:14:49
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:09:25
User entered '15:55'	Son Do (b) (4)	04 Nov 2020 16:10:03

FDA-CBER-2022-1614-2893788

US3642086
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:14:49
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered '02 Sep 2020 15:55'	System	04 Nov 2020 16:10:03

FDA-CBER-2022-1614-2893789

US3642086
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 10 Jun 2021 09:14:49
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:09:34
User entered '02 Sep 2020'	Son Do (b) (4)	04 Nov 2020 16:10:18

US3642086
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:14:49
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Son Do (b) (4)	04 Nov 2020 16:10:18

FDA-CBER-2022-1614-2893791

US3642086
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:14:49
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:09:34
User entered 'Yes (Y)'	Son Do (b) (4)	04 Nov 2020 16:10:18

FDA-CBER-2022-1614-2893792

US3642086
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:14:49
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:09:34
User entered '15:58'	Son Do (b) (4)	04 Nov 2020 16:10:18

US3642086
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:14:49
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered '02 Sep 2020 15:58'	System	04 Nov 2020 16:10:18

FDA-CBER-2022-1614-2893794

US3642086
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:14:49
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Son Do (b) (4)	04 Nov 2020 16:10:18

FDA-CBER-2022-1614-2893795

US3642086
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:14:49
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:09:34
User entered 'No (N)'	Son Do (b) (4)	04 Nov 2020 16:10:18

US3642086
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:14:49
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:09:34
User entered empty.	Son Do (b) (4)	04 Nov 2020 16:10:18

FDA-CBER-2022-1614-2893797

US3642086
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:14:49
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered empty.	System	04 Nov 2020 16:10:18

US3642086
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 10 Jun 2021 09:14:49
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:09:41
User entered 'Yes (Y)'	Colleen McLellan (b) (4) (b) (4)	10 Sep 2020 00:55:59

US3642086
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 10 Jun 2021 09:14:49
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered '1'	System	10 Sep 2020 00:55:59

FDA-CBER-2022-1614-2893800

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	02 Sep 2020 23:51:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 23:51:18

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

FDA-CBER-2022-1614-2893802

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

FDA-CBER-2022-1614-2893806

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

FDA-CBER-2022-1614-2893807

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '02 Sep 2020 17:00'	System	06 Nov 2020 23:00:49
User entered '02 Sep 2020 11:00'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893808

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '02 Sep 2020 19:30'	System	06 Nov 2020 23:00:49
User entered '02 Sep 2020 13:30'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893809

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	02 Sep 2020 23:51:18
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 23:51:18

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-02T16:58:35', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'd1d4c551-d6ba-4c1c-adb3-0add9029eb03'	System	02 Sep 2020 23:58:56
User entered 'Yes (Y)'	System	02 Sep 2020 23:58:56

FDA-CBER-2022-1614-2893811

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-02T16:58:43', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'd1d4c551-d6ba-4c1c-adb3-0add9029eb03'	System	02 Sep 2020 23:58:56
User entered '98.5'	System	02 Sep 2020 23:58:56

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-02T16:58:48', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'd1d4c551-d6ba-4c1c-adb3-0add9029eb03'	System	02 Sep 2020 23:58:56
User entered 'No (N)'	System	02 Sep 2020 23:58:56

FDA-CBER-2022-1614-2893813

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-02T16:58:52', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'd1d4c551-d6ba-4c1c-adb3-0add9029eb03'	System	02 Sep 2020 23:58:56
User entered '02 Sep 2020 16:58'	System	02 Sep 2020 23:58:56

FDA-CBER-2022-1614-2893814

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '02 Sep 2020 14:25'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893815

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893816

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	02 Sep 2020 23:51:18
User entered 'Day 2'	System	02 Sep 2020 23:51:18

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:14:49
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-03T12:19:44', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'bb28292c-6e6e-4b74-a6db-21d8849dabba'	System	03 Sep 2020 19:20:06
User entered 'Yes (Y)'	System	03 Sep 2020 19:20:06

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:14:49
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-03T12:19:52', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'bb28292c-6e6e-4b74-a6db-21d8849dabba'	System	03 Sep 2020 19:20:06
User entered '98.3'	System	03 Sep 2020 19:20:06

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:14:49
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-03T12:19:57', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'bb28292c-6e6e-4b74-a6db-21d8849dabba'	System	03 Sep 2020 19:20:06
User entered 'No (N)'	System	03 Sep 2020 19:20:06

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:14:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-03T12:20:03', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'bb28292c-6e6e-4b74-a6db-21d8849dabba'	System	03 Sep 2020 19:20:06
User entered '03 Sep 2020 12:20'	System	03 Sep 2020 19:20:06

FDA-CBER-2022-1614-2893821

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893822

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893823

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	02 Sep 2020 23:51:18
User entered 'Day 3'	System	02 Sep 2020 23:51:18

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:14:49
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-04T12:09:19', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '97c7ffd7-39c3-4003-acbd-154fb051ca96'	System	04 Sep 2020 19:09:43
User entered 'Yes (Y)'	System	04 Sep 2020 19:09:43

FDA-CBER-2022-1614-2893825

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:14:49
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-04T12:09:30', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '97c7ffd7-39c3-4003-acbd-154fb051ca96'	System	04 Sep 2020 19:09:43
User entered '98.2'	System	04 Sep 2020 19:09:43

FDA-CBER-2022-1614-2893826

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:14:49
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-04T12:09:34', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '97c7ffd7-39c3-4003-acbd-154fb051ca96'	System	04 Sep 2020 19:09:43
User entered 'No (N)'	System	04 Sep 2020 19:09:43

FDA-CBER-2022-1614-2893827

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:14:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-04T12:09:40', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '97c7ffd7-39c3-4003-acbd-154fb051ca96'	System	04 Sep 2020 19:09:43
User entered '04 Sep 2020 12:09'	System	04 Sep 2020 19:09:43

FDA-CBER-2022-1614-2893828

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893829

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893830

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	02 Sep 2020 23:51:18
User entered 'Day 4'	System	02 Sep 2020 23:51:18

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:14:49
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-05T15:18:43', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'a1e1ea31-3bb3-42c4-a25c-e5e108a9f1d6'	System	05 Sep 2020 22:19:01
User entered 'Yes (Y)'	System	05 Sep 2020 22:19:01

FDA-CBER-2022-1614-2893832

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:14:49
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-05T15:18:54', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'a1e1ea31-3bb3-42c4-a25c-e5e108a9f1d6'	System	05 Sep 2020 22:19:01
User entered '98.7'	System	05 Sep 2020 22:19:01

FDA-CBER-2022-1614-2893833

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:14:49
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-05T15:18:56', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'a1e1ea31-3bb3-42c4-a25c-e5e108a9f1d6'	System	05 Sep 2020 22:19:01
User entered 'No (N)'	System	05 Sep 2020 22:19:01

FDA-CBER-2022-1614-2893834

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:14:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-05T15:19:00', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'a1e1ea31-3bb3-42c4-a25c-e5e108a9f1d6'	System	05 Sep 2020 22:19:01
User entered '05 Sep 2020 15:19'	System	05 Sep 2020 22:19:01

FDA-CBER-2022-1614-2893835

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893836

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893837

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	02 Sep 2020 23:51:18
User entered 'Day 5'	System	02 Sep 2020 23:51:18

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:14:49
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-06T18:04:30', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '6814c9a0-84d4-4204-876a-97ead91cd72c'	System	07 Sep 2020 01:04:49
User entered 'Yes (Y)'	System	07 Sep 2020 01:04:49

FDA-CBER-2022-1614-2893839

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:14:49
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-06T18:04:37', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '6814c9a0-84d4-4204-876a-97ead91cd72c'	System	07 Sep 2020 01:04:49
User entered '98.4'	System	07 Sep 2020 01:04:49

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:14:49
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-06T18:04:43', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '6814c9a0-84d4-4204-876a-97ead91cd72c'	System	07 Sep 2020 01:04:49
User entered 'No (N)'	System	07 Sep 2020 01:04:49

FDA-CBER-2022-1614-2893841

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:14:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-06T18:04:46', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '6814c9a0-84d4-4204-876a-97ead91cd72c'	System	07 Sep 2020 01:04:49
User entered '06 Sep 2020 18:04'	System	07 Sep 2020 01:04:49

FDA-CBER-2022-1614-2893842

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893843

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893844

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	02 Sep 2020 23:51:18
User entered 'Day 6'	System	02 Sep 2020 23:51:18

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:14:49
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-07T17:20:52', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '2e70d677-013e-4cd7-861d-9e095cf4961f'	System	08 Sep 2020 00:21:08
User entered 'Yes (Y)'	System	08 Sep 2020 00:21:08

FDA-CBER-2022-1614-2893846

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:14:49
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-07T17:20:58', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '2e70d677-013e-4cd7-861d-9e095cf4961f'	System	08 Sep 2020 00:21:08
User entered '98.0'	System	08 Sep 2020 00:21:08

FDA-CBER-2022-1614-2893847

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:14:49
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-07T17:21:00', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '2e70d677-013e-4cd7-861d-9e095cf4961f'	System	08 Sep 2020 00:21:08
User entered 'No (N)'	System	08 Sep 2020 00:21:08

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:14:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-07T17:21:04', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '2e70d677-013e-4cd7-861d-9e095cf4961f'	System	08 Sep 2020 00:21:08
User entered '07 Sep 2020 17:21'	System	08 Sep 2020 00:21:08

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893850

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893851

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	02 Sep 2020 23:51:18
User entered 'Day 7'	System	02 Sep 2020 23:51:18

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:14:49
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-08T17:32:43', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '6dc0ff27-4d33-4b14-96c8-c7ac662e87e6'	System	09 Sep 2020 00:33:04
User entered 'Yes (Y)'	System	09 Sep 2020 00:33:04

FDA-CBER-2022-1614-2893853

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:14:49
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-08T17:32:53', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '6dc0ff27-4d33-4b14-96c8-c7ac662e87e6'	System	09 Sep 2020 00:33:04
User entered '97.9'	System	09 Sep 2020 00:33:04

FDA-CBER-2022-1614-2893854

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:14:49
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-08T17:32:56', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '6dc0ff27-4d33-4b14-96c8-c7ac662e87e6'	System	09 Sep 2020 00:33:04
User entered 'No (N)'	System	09 Sep 2020 00:33:04

FDA-CBER-2022-1614-2893855

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:14:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-08T17:32:58', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '6dc0ff27-4d33-4b14-96c8-c7ac662e87e6'	System	09 Sep 2020 00:33:04
User entered '08 Sep 2020 17:32'	System	09 Sep 2020 00:33:04

FDA-CBER-2022-1614-2893856

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893857

US3642086
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893858

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	02 Sep 2020 23:51:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 23:51:18

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
Please record - **REDNESS AT INJECTION SITE (in mm)**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

FDA-CBER-2022-1614-2893863

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

FDA-CBER-2022-1614-2893864

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

FDA-CBER-2022-1614-2893866

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '02 Sep 2020 17:00'	System	06 Nov 2020 23:00:49
User entered '02 Sep 2020 11:00'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893867

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '02 Sep 2020 19:30'	System	06 Nov 2020 23:00:49
User entered '02 Sep 2020 13:30'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893868

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	02 Sep 2020 23:51:18
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 23:51:18

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-02T16:59:14', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '89590dd1-1e47-4fdc-a2dc-8acdab4ac2ae'	System	02 Sep 2020 23:59:38
User entered 'None (1)'	System	02 Sep 2020 23:59:38

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-02T16:59:20', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '89590dd1-1e47-4fdc-a2dc-8acdab4ac2ae'	System	02 Sep 2020 23:59:38
User entered 'No (N)'	System	02 Sep 2020 23:59:38

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US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-02T16:59:23', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '89590dd1-1e47-4fdc-a2dc-8acdab4ac2ae'	System	02 Sep 2020 23:59:38
User entered 'No (N)'	System	02 Sep 2020 23:59:38

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-02T16:59:29', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '89590dd1-1e47-4fdc-a2dc-8acdab4ac2ae'	System	02 Sep 2020 23:59:38
User entered 'None (1)'	System	02 Sep 2020 23:59:38

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-02T16:59:32', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '89590dd1-1e47-4fdc-a2dc-8acdab4ac2ae'	System	02 Sep 2020 23:59:38
User entered '02 Sep 2020 16:59'	System	02 Sep 2020 23:59:38

FDA-CBER-2022-1614-2893874

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '02 Sep 2020 14:25'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893875

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893876

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	02 Sep 2020 23:51:18
User entered 'Day 2'	System	02 Sep 2020 23:51:18

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:14:49
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-03T12:20:11', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'cfc9b2f9-2719-4ed5-a0ea-f56b8a3f3818'	System	03 Sep 2020 19:20:26
User entered 'None (1)'	System	03 Sep 2020 19:20:26

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:14:49
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-03T12:20:14', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'cfc9b2f9-2719-4ed5-a0ea-f56b8a3f3818'	System	03 Sep 2020 19:20:26
User entered 'No (N)'	System	03 Sep 2020 19:20:26

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:14:49
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-03T12:20:17', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'cfc9b2f9-2719-4ed5-a0ea-f56b8a3f3818'	System	03 Sep 2020 19:20:26
User entered 'No (N)'	System	03 Sep 2020 19:20:26

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US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:14:49
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-03T12:20:20', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'cfc9b2f9-2719-4ed5-a0ea-f56b8a3f3818'	System	03 Sep 2020 19:20:26
User entered 'None (1)'	System	03 Sep 2020 19:20:26

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:14:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-03T12:20:23', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'cfc9b2f9-2719-4ed5-a0ea-f56b8a3f3818'	System	03 Sep 2020 19:20:26
User entered '03 Sep 2020 12:20'	System	03 Sep 2020 19:20:26

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 23:51:18

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US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893884

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	02 Sep 2020 23:51:18
User entered 'Day 3'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893885

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:14:49
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-04T12:09:45', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'f641c3c1-60f0-43b0-ae44-8d7446765f49'	System	04 Sep 2020 19:10:01
User entered 'None (1)'	System	04 Sep 2020 19:10:01

FDA-CBER-2022-1614-2893886

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:14:49
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-04T12:09:48', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'f641c3c1-60f0-43b0-ae44-8d7446765f49'	System	04 Sep 2020 19:10:01
User entered 'No (N)'	System	04 Sep 2020 19:10:01

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:14:49
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-04T12:09:51', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'f641c3c1-60f0-43b0-ae44-8d7446765f49'	System	04 Sep 2020 19:10:01
User entered 'No (N)'	System	04 Sep 2020 19:10:01

FDA-CBER-2022-1614-2893888

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:14:49
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-04T12:09:54', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'f641c3c1-60f0-43b0-ae44-8d7446765f49'	System	04 Sep 2020 19:10:01
User entered 'None (1)'	System	04 Sep 2020 19:10:01

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:14:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-04T12:09:57', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'f641c3c1-60f0-43b0-ae44-8d7446765f49'	System	04 Sep 2020 19:10:01
User entered '04 Sep 2020 12:09'	System	04 Sep 2020 19:10:01

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US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893891

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893892

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	02 Sep 2020 23:51:18
User entered 'Day 4'	System	02 Sep 2020 23:51:18

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:14:49
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-05T15:19:04', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'be5141c9-191c-48e8-b36f-d8ebfa1ba10f'	System	05 Sep 2020 22:19:22
User entered 'None (1)'	System	05 Sep 2020 22:19:22

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:14:49
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-05T15:19:07', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'be5141c9-191c-48e8-b36f-d8ebfa1ba10f'	System	05 Sep 2020 22:19:22
User entered 'No (N)'	System	05 Sep 2020 22:19:22

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:14:49
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-05T15:19:14', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'be5141c9-191c-48e8-b36f-d8ebfa1ba10f'	System	05 Sep 2020 22:19:22
User entered 'No (N)'	System	05 Sep 2020 22:19:22

FDA-CBER-2022-1614-2893896

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:14:49
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-05T15:19:18', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'be5141c9-191c-48e8-b36f-d8ebfa1ba10f'	System	05 Sep 2020 22:19:22
User entered 'None (1)'	System	05 Sep 2020 22:19:22

FDA-CBER-2022-1614-2893897

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:14:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-05T15:19:21', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'be5141c9-191c-48e8-b36f-d8ebfa1ba10f'	System	05 Sep 2020 22:19:22
User entered '05 Sep 2020 15:19'	System	05 Sep 2020 22:19:22

FDA-CBER-2022-1614-2893898

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893899

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893900

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	02 Sep 2020 23:51:18
User entered 'Day 5'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893901

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:14:49
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-06T18:04:49', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'fd685832-ae59-4e59-b68c-8e20774c6962'	System	07 Sep 2020 01:05:11
User entered 'None (1)'	System	07 Sep 2020 01:05:11

FDA-CBER-2022-1614-2893902

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:14:49
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-06T18:04:52', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'fd685832-ae59-4e59-b68c-8e20774c6962'	System	07 Sep 2020 01:05:11
User entered 'No (N)'	System	07 Sep 2020 01:05:11

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:14:49
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-06T18:04:54', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'fd685832-ae59-4e59-b68c-8e20774c6962'	System	07 Sep 2020 01:05:11
User entered 'No (N)'	System	07 Sep 2020 01:05:11

FDA-CBER-2022-1614-2893904

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:14:49
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-06T18:05:03', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'fd685832-ae59-4e59-b68c-8e20774c6962'	System	07 Sep 2020 01:05:11
User entered 'None (1)'	System	07 Sep 2020 01:05:11

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:14:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-06T18:05:09', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'fd685832-ae59-4e59-b68c-8e20774c6962'	System	07 Sep 2020 01:05:11
User entered '06 Sep 2020 18:05'	System	07 Sep 2020 01:05:11

FDA-CBER-2022-1614-2893906

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893907

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 23:51:18

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US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	02 Sep 2020 23:51:18
User entered 'Day 6'	System	02 Sep 2020 23:51:18

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:14:49
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-07T17:21:09', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '079b79d6-108f-4aba-9ebf-11eed9f77776'	System	08 Sep 2020 00:21:24
User entered 'None (1)'	System	08 Sep 2020 00:21:24

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:14:49
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-07T17:21:14', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '079b79d6-108f-4aba-9ebf-11eed9f77776'	System	08 Sep 2020 00:21:24
User entered 'No (N)'	System	08 Sep 2020 00:21:24

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:14:49
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-07T17:21:16', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '079b79d6-108f-4aba-9ebf-11eed9f77776'	System	08 Sep 2020 00:21:24
User entered 'No (N)'	System	08 Sep 2020 00:21:24

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:14:49
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-07T17:21:19', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '079b79d6-108f-4aba-9ebf-11eed9f77776'	System	08 Sep 2020 00:21:24
User entered 'None (1)'	System	08 Sep 2020 00:21:24

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:14:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-07T17:21:21', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '079b79d6-108f-4aba-9ebf-11eed9f77776'	System	08 Sep 2020 00:21:24
User entered '07 Sep 2020 17:21'	System	08 Sep 2020 00:21:24

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US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893915

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893916

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	02 Sep 2020 23:51:18
User entered 'Day 7'	System	02 Sep 2020 23:51:18

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:14:49
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-08T17:33:02', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'f38860a2-9b9d-48eb-8fbb-a43a34afb5cc'	System	09 Sep 2020 00:33:15
User entered 'None (1)'	System	09 Sep 2020 00:33:15

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:14:49
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-08T17:33:05', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'f38860a2-9b9d-48eb-8fbb-a43a34afb5cc'	System	09 Sep 2020 00:33:15
User entered 'No (N)'	System	09 Sep 2020 00:33:15

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:14:49
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-08T17:33:07', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'f38860a2-9b9d-48eb-8fbb-a43a34afb5cc'	System	09 Sep 2020 00:33:15
User entered 'No (N)'	System	09 Sep 2020 00:33:15

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:14:49
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-08T17:33:10', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'f38860a2-9b9d-48eb-8fbb-a43a34afb5cc'	System	09 Sep 2020 00:33:15
User entered 'None (1)'	System	09 Sep 2020 00:33:15

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US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:14:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-08T17:33:13', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'f38860a2-9b9d-48eb-8fbb-a43a34afb5cc'	System	09 Sep 2020 00:33:15
User entered '08 Sep 2020 17:33'	System	09 Sep 2020 00:33:15

FDA-CBER-2022-1614-2893922

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893923

US3642086
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893924

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	02 Sep 2020 23:51:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893925

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

FDA-CBER-2022-1614-2893926

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

FDA-CBER-2022-1614-2893927

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

FDA-CBER-2022-1614-2893928

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

FDA-CBER-2022-1614-2893929

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

FDA-CBER-2022-1614-2893930

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

FDA-CBER-2022-1614-2893931

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

FDA-CBER-2022-1614-2893933

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '02 Sep 2020 17:00'	System	06 Nov 2020 23:00:49
User entered '02 Sep 2020 11:00'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893934

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '02 Sep 2020 19:30'	System	06 Nov 2020 23:00:49
User entered '02 Sep 2020 13:30'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893935

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	02 Sep 2020 23:51:18
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 23:51:18

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-02T16:59:39', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '35b2838a-65d7-4407-8b03-501c9f181095'	System	02 Sep 2020 23:59:58
User entered 'None (0)'	System	02 Sep 2020 23:59:58

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-02T16:59:41', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '35b2838a-65d7-4407-8b03-501c9f181095'	System	02 Sep 2020 23:59:58
User entered 'None (0)'	System	02 Sep 2020 23:59:58

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-02T16:59:43', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '35b2838a-65d7-4407-8b03-501c9f181095'	System	02 Sep 2020 23:59:58
User entered 'None (0)'	System	02 Sep 2020 23:59:58

FDA-CBER-2022-1614-2893939

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-02T16:59:46', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '35b2838a-65d7-4407-8b03-501c9f181095'	System	02 Sep 2020 23:59:58
User entered 'None (0)'	System	02 Sep 2020 23:59:58

FDA-CBER-2022-1614-2893940

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-02T16:59:47', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '35b2838a-65d7-4407-8b03-501c9f181095'	System	02 Sep 2020 23:59:58
User entered 'None (0)'	System	02 Sep 2020 23:59:58

FDA-CBER-2022-1614-2893941

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-02T16:59:49', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '35b2838a-65d7-4407-8b03-501c9f181095'	System	02 Sep 2020 23:59:58
User entered 'None (0)'	System	02 Sep 2020 23:59:58

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-02T16:59:52', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '35b2838a-65d7-4407-8b03-501c9f181095'	System	02 Sep 2020 23:59:58
User entered 'No (N)'	System	02 Sep 2020 23:59:58

FDA-CBER-2022-1614-2893943

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-02T16:59:54', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '35b2838a-65d7-4407-8b03-501c9f181095'	System	02 Sep 2020 23:59:58
User entered '02 Sep 2020 16:59'	System	02 Sep 2020 23:59:58

FDA-CBER-2022-1614-2893944

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '02 Sep 2020 14:25'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893945

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893946

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	02 Sep 2020 23:51:18
User entered 'Day 2'	System	02 Sep 2020 23:51:18

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:14:49
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-03T12:20:30', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'b2d8a519-d939-4016-8b07-21be4d9de0b6'	System	03 Sep 2020 19:20:55
User entered 'None (0)'	System	03 Sep 2020 19:20:55

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:14:49
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-03T12:20:32', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'b2d8a519-d939-4016-8b07-21be4d9de0b6'	System	03 Sep 2020 19:20:55
User entered 'None (0)'	System	03 Sep 2020 19:20:55

FDA-CBER-2022-1614-2893949

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:14:49
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-03T12:20:34', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'b2d8a519-d939-4016-8b07-21be4d9de0b6'	System	03 Sep 2020 19:20:55
User entered 'None (0)'	System	03 Sep 2020 19:20:55

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:14:49
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-03T12:20:38', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'b2d8a519-d939-4016-8b07-21be4d9de0b6'	System	03 Sep 2020 19:20:55
User entered 'None (0)'	System	03 Sep 2020 19:20:55

FDA-CBER-2022-1614-2893951

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:14:49
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-03T12:20:40', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'b2d8a519-d939-4016-8b07-21be4d9de0b6'	System	03 Sep 2020 19:20:55
User entered 'None (0)'	System	03 Sep 2020 19:20:55

FDA-CBER-2022-1614-2893952

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:14:49
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-03T12:20:42', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'b2d8a519-d939-4016-8b07-21be4d9de0b6'	System	03 Sep 2020 19:20:55
User entered 'None (0)'	System	03 Sep 2020 19:20:55

FDA-CBER-2022-1614-2893953

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:14:49
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-03T12:20:47', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'b2d8a519-d939-4016-8b07-21be4d9de0b6'	System	03 Sep 2020 19:20:55
User entered 'No (N)'	System	03 Sep 2020 19:20:55

FDA-CBER-2022-1614-2893954

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:14:49
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-03T12:20:51', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'b2d8a519-d939-4016-8b07-21be4d9de0b6'	System	03 Sep 2020 19:20:55
User entered '03 Sep 2020 12:20'	System	03 Sep 2020 19:20:55

FDA-CBER-2022-1614-2893955

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893956

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893957

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	02 Sep 2020 23:51:18
User entered 'Day 3'	System	02 Sep 2020 23:51:18

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:14:49
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-04T12:10:03', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '2b07baf3-64aa-43b2-905e-af9ef68f48fd'	System	04 Sep 2020 19:10:25
User entered 'None (0)'	System	04 Sep 2020 19:10:25

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:14:49
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-04T12:10:05', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '2b07baf3-64aa-43b2-905e-af9ef68f48fd'	System	04 Sep 2020 19:10:25
User entered 'None (0)'	System	04 Sep 2020 19:10:25

FDA-CBER-2022-1614-2893960

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:14:49
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-04T12:10:08', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '2b07baf3-64aa-43b2-905e-af9ef68f48fd'	System	04 Sep 2020 19:10:25
User entered 'None (0)'	System	04 Sep 2020 19:10:25

FDA-CBER-2022-1614-2893961

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:14:49
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-04T12:10:10', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '2b07baf3-64aa-43b2-905e-af9ef68f48fd'	System	04 Sep 2020 19:10:25
User entered 'None (0)'	System	04 Sep 2020 19:10:25

FDA-CBER-2022-1614-2893962

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:14:49
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-04T12:10:13', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '2b07baf3-64aa-43b2-905e-af9ef68f48fd'	System	04 Sep 2020 19:10:25
User entered 'None (0)'	System	04 Sep 2020 19:10:25

FDA-CBER-2022-1614-2893963

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:14:49
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-04T12:10:15', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '2b07baf3-64aa-43b2-905e-af9ef68f48fd'	System	04 Sep 2020 19:10:25
User entered 'None (0)'	System	04 Sep 2020 19:10:25

FDA-CBER-2022-1614-2893964

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:14:49
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-04T12:10:20', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '2b07baf3-64aa-43b2-905e-af9ef68f48fd'	System	04 Sep 2020 19:10:25
User entered 'No (N)'	System	04 Sep 2020 19:10:25

FDA-CBER-2022-1614-2893965

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:14:49
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-04T12:10:23', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '2b07baf3-64aa-43b2-905e-af9ef68f48fd'	System	04 Sep 2020 19:10:25
User entered '04 Sep 2020 12:10'	System	04 Sep 2020 19:10:25

FDA-CBER-2022-1614-2893966

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893967

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893968

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	02 Sep 2020 23:51:18
User entered 'Day 4'	System	02 Sep 2020 23:51:18

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:14:49
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-05T15:19:26', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'a1fba12b-e045-41f0-aa0f-ec07a921986e'	System	05 Sep 2020 22:19:56
User entered 'None (0)'	System	05 Sep 2020 22:19:56

FDA-CBER-2022-1614-2893970

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:14:49
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-05T15:19:28', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'a1fba12b-e045-41f0-aa0f-ec07a921986e'	System	05 Sep 2020 22:19:56
User entered 'None (0)'	System	05 Sep 2020 22:19:56

FDA-CBER-2022-1614-2893971

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:14:49
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-05T15:19:33', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'a1fba12b-e045-41f0-aa0f-ec07a921986e'	System	05 Sep 2020 22:19:56
User entered 'None (0)'	System	05 Sep 2020 22:19:56

FDA-CBER-2022-1614-2893972

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:14:49
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-05T15:19:38', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'a1fba12b-e045-41f0-aa0f-ec07a921986e'	System	05 Sep 2020 22:19:56
User entered 'None (0)'	System	05 Sep 2020 22:19:56

FDA-CBER-2022-1614-2893973

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:14:49
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-05T15:19:41', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'a1fba12b-e045-41f0-aa0f-ec07a921986e'	System	05 Sep 2020 22:19:56
User entered 'None (0)'	System	05 Sep 2020 22:19:56

FDA-CBER-2022-1614-2893974

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:14:49
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-05T15:19:43', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'a1fba12b-e045-41f0-aa0f-ec07a921986e'	System	05 Sep 2020 22:19:56
User entered 'None (0)'	System	05 Sep 2020 22:19:56

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:14:49
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-05T15:19:48', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'a1fba12b-e045-41f0-aa0f-ec07a921986e'	System	05 Sep 2020 22:19:56
User entered 'No (N)'	System	05 Sep 2020 22:19:56

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:14:49
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-05T15:19:50', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'a1fba12b-e045-41f0-aa0f-ec07a921986e'	System	05 Sep 2020 22:19:56
User entered '05 Sep 2020 15:19'	System	05 Sep 2020 22:19:56

FDA-CBER-2022-1614-2893977

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893978

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893979

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	02 Sep 2020 23:51:18
User entered 'Day 5'	System	02 Sep 2020 23:51:18

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:14:49
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-06T18:05:14', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'a55fcda3-5e37-4a1b-85ea-8ada4139a87f'	System	08 Sep 2020 00:20:54
User entered 'None (0)'	System	08 Sep 2020 00:20:54

FDA-CBER-2022-1614-2893981

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:14:49
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-06T18:05:16', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'a55fcda3-5e37-4a1b-85ea-8ada4139a87f'	System	08 Sep 2020 00:20:54
User entered 'None (0)'	System	08 Sep 2020 00:20:54

FDA-CBER-2022-1614-2893982

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:14:49
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-06T18:05:18', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'a55fcda3-5e37-4a1b-85ea-8ada4139a87f'	System	08 Sep 2020 00:20:54
User entered 'None (0)'	System	08 Sep 2020 00:20:54

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:14:49
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-06T18:05:21', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'a55fcda3-5e37-4a1b-85ea-8ada4139a87f'	System	08 Sep 2020 00:20:54
User entered 'None (0)'	System	08 Sep 2020 00:20:54

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:14:49
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-06T18:05:33', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'a55fcda3-5e37-4a1b-85ea-8ada4139a87f'	System	08 Sep 2020 00:20:54
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	08 Sep 2020 00:20:54

FDA-CBER-2022-1614-2893985

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:14:49
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-06T18:05:35', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'a55fcda3-5e37-4a1b-85ea-8ada4139a87f'	System	08 Sep 2020 00:20:54
User entered 'None (0)'	System	08 Sep 2020 00:20:54

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:14:49
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-06T18:05:41', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'a55fcda3-5e37-4a1b-85ea-8ada4139a87f'	System	08 Sep 2020 00:20:54
User entered 'No (N)'	System	08 Sep 2020 00:20:54

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:14:49
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-06T18:05:43', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'a55fcda3-5e37-4a1b-85ea-8ada4139a87f'	System	08 Sep 2020 00:20:54
User entered '06 Sep 2020 18:05'	System	08 Sep 2020 00:20:54

FDA-CBER-2022-1614-2893988

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893989

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2893990

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	02 Sep 2020 23:51:18
User entered 'Day 6'	System	02 Sep 2020 23:51:18

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:14:49
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-07T17:21:25', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'd7cb25e1-aeb4-4ea6-a0af-f4260110be8d'	System	08 Sep 2020 00:21:43
User entered 'None (0)'	System	08 Sep 2020 00:21:43

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:14:49
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-07T17:21:27', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'd7cb25e1-aeb4-4ea6-a0af-f4260110be8d'	System	08 Sep 2020 00:21:43
User entered 'None (0)'	System	08 Sep 2020 00:21:43

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:14:49
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-07T17:21:30', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'd7cb25e1-aeb4-4ea6-a0af-f4260110be8d'	System	08 Sep 2020 00:21:43
User entered 'None (0)'	System	08 Sep 2020 00:21:43

FDA-CBER-2022-1614-2893994

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:14:49
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-07T17:21:33', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'd7cb25e1-aeb4-4ea6-a0af-f4260110be8d'	System	08 Sep 2020 00:21:43
User entered 'None (0)'	System	08 Sep 2020 00:21:43

FDA-CBER-2022-1614-2893995

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:14:49
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-07T17:21:34', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'd7cb25e1-aeb4-4ea6-a0af-f4260110be8d'	System	08 Sep 2020 00:21:43
User entered 'None (0)'	System	08 Sep 2020 00:21:43

FDA-CBER-2022-1614-2893996

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:14:49
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-07T17:21:36', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'd7cb25e1-aeb4-4ea6-a0af-f4260110be8d'	System	08 Sep 2020 00:21:43
User entered 'None (0)'	System	08 Sep 2020 00:21:43

FDA-CBER-2022-1614-2893997

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:14:49
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-07T17:21:39', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'd7cb25e1-aeb4-4ea6-a0af-f4260110be8d'	System	08 Sep 2020 00:21:43
User entered 'No (N)'	System	08 Sep 2020 00:21:43

FDA-CBER-2022-1614-2893998

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:14:49
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-07T17:21:42', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'd7cb25e1-aeb4-4ea6-a0af-f4260110be8d'	System	08 Sep 2020 00:21:43
User entered '07 Sep 2020 17:21'	System	08 Sep 2020 00:21:43

FDA-CBER-2022-1614-2893999

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 23:51:18

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 23:51:18

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	02 Sep 2020 23:51:18
User entered 'Day 7'	System	02 Sep 2020 23:51:18

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:14:49
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-08T17:33:16', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'ac9864d3-b3b2-4743-8fb9-cc7712db9e3b'	System	09 Sep 2020 00:33:38
User entered 'None (0)'	System	09 Sep 2020 00:33:38

FDA-CBER-2022-1614-2894003

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:14:49
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-08T17:33:19', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'ac9864d3-b3b2-4743-8fb9-cc7712db9e3b'	System	09 Sep 2020 00:33:38
User entered 'None (0)'	System	09 Sep 2020 00:33:38

FDA-CBER-2022-1614-2894004

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:14:49
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-08T17:33:22', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'ac9864d3-b3b2-4743-8fb9-cc7712db9e3b'	System	09 Sep 2020 00:33:38
User entered 'None (0)'	System	09 Sep 2020 00:33:38

FDA-CBER-2022-1614-2894005

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:14:49
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-08T17:33:24', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'ac9864d3-b3b2-4743-8fb9-cc7712db9e3b'	System	09 Sep 2020 00:33:38
User entered 'None (0)'	System	09 Sep 2020 00:33:38

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:14:49
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-08T17:33:26', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'ac9864d3-b3b2-4743-8fb9-cc7712db9e3b'	System	09 Sep 2020 00:33:38
User entered 'None (0)'	System	09 Sep 2020 00:33:38

FDA-CBER-2022-1614-2894007

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:14:49
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-08T17:33:28', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'ac9864d3-b3b2-4743-8fb9-cc7712db9e3b'	System	09 Sep 2020 00:33:38
User entered 'None (0)'	System	09 Sep 2020 00:33:38

FDA-CBER-2022-1614-2894008

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:14:49
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-08T17:33:32', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'ac9864d3-b3b2-4743-8fb9-cc7712db9e3b'	System	09 Sep 2020 00:33:38
User entered 'No (N)'	System	09 Sep 2020 00:33:38

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:14:49
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-09-08T17:33:34', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'ac9864d3-b3b2-4743-8fb9-cc7712db9e3b'	System	09 Sep 2020 00:33:38
User entered '08 Sep 2020 17:33'	System	09 Sep 2020 00:33:38

FDA-CBER-2022-1614-2894010

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2894011

US3642086
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 23:51:18

FDA-CBER-2022-1614-2894012

US3642086
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:35:13
User entered 'Yes (Y)'	Colleen McLellan (b) (4) (b) (4)	10 Sep 2020 00:56:16

US3642086
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:35:13
User entered '9 Sep 2020'	Colleen McLellan (b) (4) (b) (4)	10 Sep 2020 00:56:16

FDA-CBER-2022-1614-2894014

US3642086
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:35:13
User entered 'Contact Made (CONTACT MADE)'	Colleen McLellan (b) (4) (b) (4)	10 Sep 2020 00:56:16

US3642086
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:35:13
User entered empty.	Colleen McLellan (b) (4) (b) (4)	10 Sep 2020 00:56:16

FDA-CBER-2022-1614-2894016

US3642086
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:14:49
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:35:16
User entered 'Yes (Y)'	Colleen McLellan (b) (4) (b) (4)	10 Sep 2020 00:56:22

US3642086
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:14:49
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered '1'	System	10 Sep 2020 00:56:22

FDA-CBER-2022-1614-2894018

US3642086
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:35:30
User entered 'Yes (Y)'	Colleen McLellan (b) (4) (b) (4)	17 Sep 2020 20:27:27

US3642086
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:35:30
User entered '17 Sep 2020'	Colleen McLellan (b) (4) (b) (4)	17 Sep 2020 20:27:27

US3642086
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:35:30
User entered 'Contact Made (CONTACT MADE)'	Colleen McLellan (b) (4) (b) (4)	17 Sep 2020 20:27:27

US3642086
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:35:30
User entered empty.	Colleen McLellan (b) (4) (b) (4)	17 Sep 2020 20:27:27

FDA-CBER-2022-1614-2894022

US3642086
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:14:49
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:36:06
User entered 'Yes (Y)'	Colleen McLellan (b) (4) (b) (4)	17 Sep 2020 20:27:39

US3642086
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:14:49
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered '1'	System	17 Sep 2020 20:27:39

US3642086
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:36:20
User entered 'Yes (Y)'	Nancy Tang (b) (4)	25 Sep 2020 16:57:13

US3642086
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:36:20
User entered '25 Sep 2020'	Nancy Tang (b) (4)	25 Sep 2020 16:57:13

US3642086
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:36:20
User entered 'Contact Made (CONTACT MADE)'	Nancy Tang (b) (4)	25 Sep 2020 16:57:13

US3642086
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:36:20
User entered empty.	Nancy Tang (b) (4)	25 Sep 2020 16:57:13

FDA-CBER-2022-1614-2894028

US3642086
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:14:49
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:36:23
User entered 'Yes (Y)'	Nancy Tang (b) (4)	25 Sep 2020 16:57:18

FDA-CBER-2022-1614-2894029

US3642086
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:14:49
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered '1'	System	25 Sep 2020 16:57:18

US3642086
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:39:59
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	01 Oct 2020 21:01:21

US3642086
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:39:59
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 1OCT2020 is reported under Visit 2 Day 29visit 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).		10 Nov 2020 15:24:39
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 1OCT2020 is reported under Visit 2 Day 29visit 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 'added' (Site from DM).	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 23:01:35
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 1OCT2020 is reported under Visit 2 Day 29visit 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)	23 Oct 2020 08:37:47
User entered '1 Oct 2020'	Megan Loughran (b) (4) (b) (4)	01 Oct 2020 21:01:21

US3642086
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:39:59
User entered 'Clinic (Clinic)'	Megan Loughran (b) (4) (b) (4)	01 Oct 2020 21:01:21

US3642086
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered 'VISIT2'	System	01 Oct 2020 21:01:21

FDA-CBER-2022-1614-2894034

US3642086
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User accepted default value 'Pre-Dose (PREDOSE)'	Son Do (b) (4)	05 Oct 2020 16:39:38

FDA-CBER-2022-1614-2894035

US3642086
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:40:44
User entered 'Yes (Y)'	Son Do (b) (4)	05 Oct 2020 16:39:38

FDA-CBER-2022-1614-2894036

US3642086
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:40:44
User entered '01 Oct 2020'	Son Do (b) (4)	05 Oct 2020 16:39:38

US3642086
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:40:44
User entered '13:45'	Son Do (b) (4)	05 Oct 2020 16:39:38

FDA-CBER-2022-1614-2894038

US3642086
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered '01 Oct 2020 13:45'	System	05 Oct 2020 16:39:38

FDA-CBER-2022-1614-2894039

US3642086
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:40:44
User entered '98.3' F	Son Do (b) (4)	05 Oct 2020 16:39:38

FDA-CBER-2022-1614-2894040

US3642086
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:40:44
User entered 'Oral (Oral)'	Son Do (b) (4)	05 Oct 2020 16:39:38

FDA-CBER-2022-1614-2894041

US3642086
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:40:44
User entered empty.	Son Do (b) (4)	05 Oct 2020 16:39:38

FDA-CBER-2022-1614-2894042

US3642086
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:40:44
User entered '75'	Son Do (b) (4)	05 Oct 2020 16:39:38

FDA-CBER-2022-1614-2894043

US3642086
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered 'bpm'	System	05 Oct 2020 16:39:38

FDA-CBER-2022-1614-2894044

US3642086
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:40:44
User entered '16'	Son Do (b) (4)	05 Oct 2020 16:39:38

FDA-CBER-2022-1614-2894045

US3642086
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered 'breaths/min'	System	05 Oct 2020 16:39:38

FDA-CBER-2022-1614-2894046

US3642086
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:40:44
User entered '109'	Son Do (b) (4)	05 Oct 2020 16:39:38

FDA-CBER-2022-1614-2894047

US3642086
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered 'mmHg'	System	05 Oct 2020 16:39:38

FDA-CBER-2022-1614-2894048

US3642086
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:40:44
User entered '75'	Son Do (b) (4)	05 Oct 2020 16:39:38

FDA-CBER-2022-1614-2894049

US3642086
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered 'mmHg'	System	05 Oct 2020 16:39:38

FDA-CBER-2022-1614-2894050

US3642086
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User accepted default value 'Post-Dose (POSTDOSE)'	Son Do (b) (4)	05 Oct 2020 16:39:38

FDA-CBER-2022-1614-2894051

US3642086
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:40:47
User entered 'Yes (Y)'	Son Do (b) (4)	05 Oct 2020 16:39:38

FDA-CBER-2022-1614-2894052

US3642086
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:40:47
User entered '01 Oct 2020'	Son Do (b) (4)	05 Oct 2020 16:39:38

US3642086
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:40:47
User entered '15:55'	Son Do (b) (4)	05 Oct 2020 16:39:38

FDA-CBER-2022-1614-2894054

US3642086
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered '01 Oct 2020 15:55'	System	05 Oct 2020 16:39:38

FDA-CBER-2022-1614-2894055

US3642086
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:40:47
User entered '98.3' F	Son Do (b) (4)	05 Oct 2020 16:39:38

US3642086
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:40:47
User entered 'Oral (Oral)'	Son Do (b) (4)	05 Oct 2020 16:39:38

FDA-CBER-2022-1614-2894057

US3642086
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:40:47
User entered empty.	Son Do (b) (4)	05 Oct 2020 16:39:38

FDA-CBER-2022-1614-2894058

US3642086
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:40:47
User entered '71'	Son Do (b) (4)	05 Oct 2020 16:39:38

FDA-CBER-2022-1614-2894059

US3642086
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered 'bpm'	System	05 Oct 2020 16:39:38

FDA-CBER-2022-1614-2894060

US3642086
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:40:47
User entered '16'	Son Do (b) (4)	05 Oct 2020 16:39:38

US3642086
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered 'breaths/min'	System	05 Oct 2020 16:39:38

US3642086
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:40:47
User entered '121'	Son Do (b) (4)	05 Oct 2020 16:39:38

FDA-CBER-2022-1614-2894063

US3642086
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered 'mmHg'	System	05 Oct 2020 16:39:38

FDA-CBER-2022-1614-2894064

US3642086
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:40:47
User entered '78'	Son Do (b) (4)	05 Oct 2020 16:39:38

FDA-CBER-2022-1614-2894065

US3642086
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered 'mmHg'	System	05 Oct 2020 16:39:38

FDA-CBER-2022-1614-2894066

US3642086
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:14:49
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:40:57
User entered 'Yes (Y)'	Son Do (b) (4)	05 Oct 2020 16:39:46

US3642086
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:14:49
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:40:57
User entered '01 Oct 2020'	Son Do (b) (4)	05 Oct 2020 16:39:46

FDA-CBER-2022-1614-2894068

US3642086
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User closed query 'Per GCL Lab Recon: GCL has Visit 2 Day 29 immunogenicity sample with date of 01 OCT 2020 however, sample is not recorded in EDC. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 10:27:32
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:41:14
Query 'Per GCL Lab Recon: GCL has Visit 2 Day 29 immunogenicity sample with date of 01 OCT 2020 however, sample is not recorded in EDC. Please review and reconcile.' answered with 'added' (Site from DM).	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 23:01:44
User opened query 'Per GCL Lab Recon: GCL has Visit 2 Day 29 immunogenicity sample with date of 01 OCT 2020 however, sample is not recorded in EDC. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 14:38:46
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	01 Oct 2020 22:22:39

US3642086
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:41:14
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Oct 2020 22:22:39

US3642086
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:41:14
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Oct 2020 22:22:39

US3642086
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered 'MRNA-1273 OR PLACEBO'	System	01 Oct 2020 22:22:39

US3642086
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:41:14
User entered '1 Oct 2020'	Megan Loughran (b) (4) (b) (4)	01 Oct 2020 22:22:39

US3642086
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:41:14
User entered '15:21'	Megan Loughran (b) (4) (b) (4)	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894074

US3642086
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered '1 Oct 2020 15:21'	System	01 Oct 2020 22:22:39

US3642086
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:41:14
User entered 'Left Arm (LEFT ARM)'	Megan Loughran (b) (4) (b) (4)	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894076

US3642086
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
DataPoint Verified.		19 Nov 2020 19:41:14
User entered 'ONCE'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894077

US3642086
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered 'INTRAMUSCULAR'	System	01 Oct 2020 22:22:39

US3642086
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:14:49
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:41:39
User entered 'Yes (Y)'	Son Do (b) (4)	04 Nov 2020 16:11:03

FDA-CBER-2022-1614-2894079

US3642086
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:14:49
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:41:39
User entered '01 Oct 2020'	Son Do (b) (4)	04 Nov 2020 16:11:03

US3642086
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:14:49
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:41:39
User entered '14:05'	Son Do (b) (4)	04 Nov 2020 16:11:03

FDA-CBER-2022-1614-2894081

US3642086
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:14:49
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered '01 Oct 2020 14:05'	System	04 Nov 2020 16:11:03

FDA-CBER-2022-1614-2894082

US3642086
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 10 Jun 2021 09:14:49
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:41:45
User entered '01 Oct 2020'	Son Do (b) (4)	04 Nov 2020 16:11:16

US3642086
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:14:49
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Son Do (b) (4)	04 Nov 2020 16:11:16

FDA-CBER-2022-1614-2894084

US3642086
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:14:49
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:41:45
User entered 'Yes (Y)'	Son Do (b) (4)	04 Nov 2020 16:11:16

US3642086
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:14:49
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:41:45
User entered '14:09'	Son Do (b) (4)	04 Nov 2020 16:11:16

US3642086
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:14:49
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered '01 Oct 2020 14:09'	System	04 Nov 2020 16:11:16

FDA-CBER-2022-1614-2894087

US3642086
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:14:49
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Son Do (b) (4)	04 Nov 2020 16:11:16

US3642086
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:14:49
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:41:45
User entered 'No (N)'	Son Do (b) (4)	04 Nov 2020 16:11:16

US3642086
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:14:49
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:41:45
User entered empty.	Son Do (b) (4)	04 Nov 2020 16:11:16

US3642086
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:14:49
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered empty.	System	04 Nov 2020 16:11:16

US3642086
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:14:49
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 01Oct2020 is reported under Visit 2 Day 29 visit 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)	21 Nov 2020 12:58:02
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:41:59
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 01Oct2020 is reported under Visit 2 Day 29 visit 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 'added' (Site from DM).	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 23:02:16
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 01Oct2020 is reported under Visit 2 Day 29 visit 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)	30 Oct 2020 10:59:16
User entered 'Yes (Y)'	Nancy Tang (b) (4)	09 Oct 2020 00:34:21

FDA-CBER-2022-1614-2894092

US3642086
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:14:49
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered '1'	System	09 Oct 2020 00:34:21

FDA-CBER-2022-1614-2894093

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	01 Oct 2020 22:22:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 22:22:39

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-01T15:41:26', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'c7f4a291-007e-4376-b98b-a0f7f4457acd'	System	01 Oct 2020 22:41:41
User entered 'Yes (Y)'	System	01 Oct 2020 22:41:41

FDA-CBER-2022-1614-2894095

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-01T15:41:33', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'c7f4a291-007e-4376-b98b-a0f7f4457acd'	System	01 Oct 2020 22:41:41
User entered '98.3'	System	01 Oct 2020 22:41:41

FDA-CBER-2022-1614-2894096

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-01T15:41:36', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'c7f4a291-007e-4376-b98b-a0f7f4457acd'	System	01 Oct 2020 22:41:41
User entered 'No (N)'	System	01 Oct 2020 22:41:41

FDA-CBER-2022-1614-2894097

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-01T15:41:39', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'c7f4a291-007e-4376-b98b-a0f7f4457acd'	System	01 Oct 2020 22:41:41
User entered '01 Oct 2020 15:41'	System	01 Oct 2020 22:41:41

FDA-CBER-2022-1614-2894098

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '01 Oct 2020 15:41'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894099

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '01 Oct 2020 18:11'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894100

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	01 Oct 2020 22:22:39
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894101

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-01T22:26:01', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'ab172d55-dde2-4d18-a973-b1856a942d1f'	System	02 Oct 2020 05:26:16
User entered 'Yes (Y)'	System	02 Oct 2020 05:26:16

FDA-CBER-2022-1614-2894102

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-01T22:26:08', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'ab172d55-dde2-4d18-a973-b1856a942d1f'	System	02 Oct 2020 05:26:16
User entered '98.7'	System	02 Oct 2020 05:26:16

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-01T22:26:10', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'ab172d55-dde2-4d18-a973-b1856a942d1f'	System	02 Oct 2020 05:26:16
User entered 'No (N)'	System	02 Oct 2020 05:26:16

FDA-CBER-2022-1614-2894104

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-01T22:26:14', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'ab172d55-dde2-4d18-a973-b1856a942d1f'	System	02 Oct 2020 05:26:16
User entered '01 Oct 2020 22:26'	System	02 Oct 2020 05:26:16

FDA-CBER-2022-1614-2894105

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '01 Oct 2020 19:06'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894106

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894107

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	01 Oct 2020 22:22:39
User entered 'Day 2'	System	01 Oct 2020 22:22:39

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:14:49
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-02T23:06:28', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'd365c877-a04c-4761-826e-2960a28632d2'	System	03 Oct 2020 06:07:28
User entered 'Yes (Y)'	System	03 Oct 2020 06:07:28

FDA-CBER-2022-1614-2894109

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:14:49
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-02T23:06:35', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'd365c877-a04c-4761-826e-2960a28632d2'	System	03 Oct 2020 06:07:28
User entered '98.9'	System	03 Oct 2020 06:07:28

FDA-CBER-2022-1614-2894110

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:14:49
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-02T23:07:10', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'd365c877-a04c-4761-826e-2960a28632d2'	System	03 Oct 2020 06:07:28
User entered 'No (N)'	System	03 Oct 2020 06:07:28

FDA-CBER-2022-1614-2894111

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:14:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-02T23:07:14', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'd365c877-a04c-4761-826e-2960a28632d2'	System	03 Oct 2020 06:07:28
User entered '02 Oct 2020 23:07'	System	03 Oct 2020 06:07:28

FDA-CBER-2022-1614-2894112

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894113

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894114

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	01 Oct 2020 22:22:39
User entered 'Day 3'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894115

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:14:49
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-03T14:21:22', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'cfadb1a0-adad-44cd-901a-79b77efeae7f'	System	03 Oct 2020 21:21:36
User entered 'Yes (Y)'	System	03 Oct 2020 21:21:36

FDA-CBER-2022-1614-2894116

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:14:49
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-03T14:21:27', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'cfadb1a0-adad-44cd-901a-79b77efeae7f'	System	03 Oct 2020 21:21:36
User entered '98.1'	System	03 Oct 2020 21:21:36

FDA-CBER-2022-1614-2894117

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:14:49
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-03T14:21:31', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'cfadb1a0-adad-44cd-901a-79b77efeae7f'	System	03 Oct 2020 21:21:36
User entered 'No (N)'	System	03 Oct 2020 21:21:36

FDA-CBER-2022-1614-2894118

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:14:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-03T14:21:33', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'cfadb1a0-adad-44cd-901a-79b77efeae7f'	System	03 Oct 2020 21:21:36
User entered '03 Oct 2020 14:21'	System	03 Oct 2020 21:21:36

FDA-CBER-2022-1614-2894119

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894120

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894121

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	01 Oct 2020 22:22:39
User entered 'Day 4'	System	01 Oct 2020 22:22:39

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:14:49
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-05T00:00:49', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '0bce6968-69e2-4845-a850-3b7a11901818'	System	05 Oct 2020 07:01:08
User entered 'Yes (Y)'	System	05 Oct 2020 07:01:08

FDA-CBER-2022-1614-2894123

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:14:49
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-05T00:00:59', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '0bce6968-69e2-4845-a850-3b7a11901818'	System	05 Oct 2020 07:01:08
User entered '97.8'	System	05 Oct 2020 07:01:08

FDA-CBER-2022-1614-2894124

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:14:49
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-05T00:01:01', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '0bce6968-69e2-4845-a850-3b7a11901818'	System	05 Oct 2020 07:01:08
User entered 'No (N)'	System	05 Oct 2020 07:01:08

FDA-CBER-2022-1614-2894125

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:14:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-05T00:01:04', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '0bce6968-69e2-4845-a850-3b7a11901818'	System	05 Oct 2020 07:01:08
User entered '05 Oct 2020 00:01'	System	05 Oct 2020 07:01:08

FDA-CBER-2022-1614-2894126

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894127

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894128

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	01 Oct 2020 22:22:39
User entered 'Day 5'	System	01 Oct 2020 22:22:39

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:14:49
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-05T13:29:39', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'd8ba33c7-7ae9-4f1f-8f1f-213f305c0e47'	System	05 Oct 2020 20:29:54
User entered 'Yes (Y)'	System	05 Oct 2020 20:29:54

FDA-CBER-2022-1614-2894130

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:14:49
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-05T13:29:46', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'd8ba33c7-7ae9-4f1f-8f1f-213f305c0e47'	System	05 Oct 2020 20:29:54
User entered '98.1'	System	05 Oct 2020 20:29:54

FDA-CBER-2022-1614-2894131

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:14:49
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-05T13:29:48', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'd8ba33c7-7ae9-4f1f-8f1f-213f305c0e47'	System	05 Oct 2020 20:29:54
User entered 'No (N)'	System	05 Oct 2020 20:29:54

FDA-CBER-2022-1614-2894132

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:14:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-05T13:29:51', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'd8ba33c7-7ae9-4f1f-8f1f-213f305c0e47'	System	05 Oct 2020 20:29:54
User entered '05 Oct 2020 13:29'	System	05 Oct 2020 20:29:54

FDA-CBER-2022-1614-2894133

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894134

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894135

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	01 Oct 2020 22:22:39
User entered 'Day 6'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894136

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:14:49
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

FDA-CBER-2022-1614-2894137

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:14:49
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:14:49
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:14:49
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

FDA-CBER-2022-1614-2894140

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:14:49
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

FDA-CBER-2022-1614-2894141

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:14:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

FDA-CBER-2022-1614-2894142

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894143

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894144

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	01 Oct 2020 22:22:39
User entered 'Day 7'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894145

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:14:49
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-07T13:15:13', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '1311bad8-8ab7-409d-a537-8f01009861bd'	System	07 Oct 2020 20:15:39
User entered 'Yes (Y)'	System	07 Oct 2020 20:15:39

FDA-CBER-2022-1614-2894146

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:14:49
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-07T13:15:29', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '1311bad8-8ab7-409d-a537-8f01009861bd'	System	07 Oct 2020 20:15:39
User entered '97.8'	System	07 Oct 2020 20:15:39

FDA-CBER-2022-1614-2894147

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:14:49
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-07T13:15:31', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '1311bad8-8ab7-409d-a537-8f01009861bd'	System	07 Oct 2020 20:15:39
User entered 'No (N)'	System	07 Oct 2020 20:15:39

FDA-CBER-2022-1614-2894148

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:14:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-07T13:15:34', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '1311bad8-8ab7-409d-a537-8f01009861bd'	System	07 Oct 2020 20:15:39
User entered '07 Oct 2020 13:15'	System	07 Oct 2020 20:15:39

FDA-CBER-2022-1614-2894149

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894150

US3642086
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894151

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	01 Oct 2020 22:22:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 22:22:39

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-01T15:41:45', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '64ae4fa6-a1ac-4af3-af65-76c350d15a87'	System	01 Oct 2020 22:41:56
User entered 'None (1)'	System	01 Oct 2020 22:41:56

FDA-CBER-2022-1614-2894153

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-01T15:41:48', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '64ae4fa6-a1ac-4af3-af65-76c350d15a87'	System	01 Oct 2020 22:41:56
User entered 'No (N)'	System	01 Oct 2020 22:41:56

FDA-CBER-2022-1614-2894154

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-01T15:41:50', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '64ae4fa6-a1ac-4af3-af65-76c350d15a87'	System	01 Oct 2020 22:41:56
User entered 'No (N)'	System	01 Oct 2020 22:41:56

FDA-CBER-2022-1614-2894155

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-01T15:41:53', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '64ae4fa6-a1ac-4af3-af65-76c350d15a87'	System	01 Oct 2020 22:41:56
User entered 'None (1)'	System	01 Oct 2020 22:41:56

FDA-CBER-2022-1614-2894156

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-01T15:41:55', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '64ae4fa6-a1ac-4af3-af65-76c350d15a87'	System	01 Oct 2020 22:41:56
User entered '01 Oct 2020 15:41'	System	01 Oct 2020 22:41:56

FDA-CBER-2022-1614-2894157

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '01 Oct 2020 15:41'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894158

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '01 Oct 2020 18:11'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894159

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	01 Oct 2020 22:22:39
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 22:22:39

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-01T22:26:22', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '86c6968a-1091-499b-bc95-56b7151de303'	System	02 Oct 2020 05:26:49
User entered 'Does not interfere with activity (2)'	System	02 Oct 2020 05:26:49

FDA-CBER-2022-1614-2894161

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-01T22:26:35', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '86c6968a-1091-499b-bc95-56b7151de303'	System	02 Oct 2020 05:26:49
User entered 'No (N)'	System	02 Oct 2020 05:26:49

FDA-CBER-2022-1614-2894162

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-01T22:26:38', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '86c6968a-1091-499b-bc95-56b7151de303'	System	02 Oct 2020 05:26:49
User entered 'No (N)'	System	02 Oct 2020 05:26:49

FDA-CBER-2022-1614-2894163

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-01T22:26:40', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '86c6968a-1091-499b-bc95-56b7151de303'	System	02 Oct 2020 05:26:49
User entered 'None (1)'	System	02 Oct 2020 05:26:49

FDA-CBER-2022-1614-2894164

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-01T22:26:46', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '86c6968a-1091-499b-bc95-56b7151de303'	System	02 Oct 2020 05:26:49
User entered '01 Oct 2020 22:26'	System	02 Oct 2020 05:26:49

FDA-CBER-2022-1614-2894165

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '01 Oct 2020 19:06'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894166

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894167

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	01 Oct 2020 22:22:39
User entered 'Day 2'	System	01 Oct 2020 22:22:39

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:14:49
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-02T23:07:23', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '25d26fdd-03b4-4068-9fba-5b79a6e2a33b'	System	03 Oct 2020 06:07:36
User entered 'None (1)'	System	03 Oct 2020 06:07:36

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:14:49
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-02T23:07:26', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '25d26fdd-03b4-4068-9fba-5b79a6e2a33b'	System	03 Oct 2020 06:07:36
User entered 'No (N)'	System	03 Oct 2020 06:07:36

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:14:49
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-02T23:07:28', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '25d26fdd-03b4-4068-9fba-5b79a6e2a33b'	System	03 Oct 2020 06:07:36
User entered 'No (N)'	System	03 Oct 2020 06:07:36

FDA-CBER-2022-1614-2894171

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:14:49
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-02T23:07:31', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '25d26fdd-03b4-4068-9fba-5b79a6e2a33b'	System	03 Oct 2020 06:07:36
User entered 'None (1)'	System	03 Oct 2020 06:07:36

FDA-CBER-2022-1614-2894172

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:14:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-02T23:07:34', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '25d26fdd-03b4-4068-9fba-5b79a6e2a33b'	System	03 Oct 2020 06:07:36
User entered '02 Oct 2020 23:07'	System	03 Oct 2020 06:07:36

FDA-CBER-2022-1614-2894173

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894174

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894175

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	01 Oct 2020 22:22:39
User entered 'Day 3'	System	01 Oct 2020 22:22:39

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:14:49
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-03T14:21:37', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'cc8fae72-ee7c-4748-94b4-0033ac95e641'	System	03 Oct 2020 21:21:49
User entered 'None (1)'	System	03 Oct 2020 21:21:49

FDA-CBER-2022-1614-2894177

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:14:49
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-03T14:21:40', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'cc8fae72-ee7c-4748-94b4-0033ac95e641'	System	03 Oct 2020 21:21:49
User entered 'No (N)'	System	03 Oct 2020 21:21:49

FDA-CBER-2022-1614-2894178

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:14:49
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-03T14:21:42', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'cc8fae72-ee7c-4748-94b4-0033ac95e641'	System	03 Oct 2020 21:21:49
User entered 'No (N)'	System	03 Oct 2020 21:21:49

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:14:49
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-03T14:21:45', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'cc8fae72-ee7c-4748-94b4-0033ac95e641'	System	03 Oct 2020 21:21:49
User entered 'None (1)'	System	03 Oct 2020 21:21:49

FDA-CBER-2022-1614-2894180

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:14:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-03T14:21:48', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'cc8fae72-ee7c-4748-94b4-0033ac95e641'	System	03 Oct 2020 21:21:49
User entered '03 Oct 2020 14:21'	System	03 Oct 2020 21:21:49

FDA-CBER-2022-1614-2894181

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894182

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894183

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	01 Oct 2020 22:22:39
User entered 'Day 4'	System	01 Oct 2020 22:22:39

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:14:49
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-05T00:01:07', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'b9a68ae4-2daa-4d11-972e-726c08a9675d'	System	05 Oct 2020 07:01:24
User entered 'None (1)'	System	05 Oct 2020 07:01:24

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:14:49
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-05T00:01:11', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'b9a68ae4-2daa-4d11-972e-726c08a9675d'	System	05 Oct 2020 07:01:24
User entered 'No (N)'	System	05 Oct 2020 07:01:24

FDA-CBER-2022-1614-2894186

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:14:49
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-05T00:01:13', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'b9a68ae4-2daa-4d11-972e-726c08a9675d'	System	05 Oct 2020 07:01:24
User entered 'No (N)'	System	05 Oct 2020 07:01:24

FDA-CBER-2022-1614-2894187

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:14:49
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-05T00:01:16', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'b9a68ae4-2daa-4d11-972e-726c08a9675d'	System	05 Oct 2020 07:01:24
User entered 'None (1)'	System	05 Oct 2020 07:01:24

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:14:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-05T00:01:19', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'b9a68ae4-2daa-4d11-972e-726c08a9675d'	System	05 Oct 2020 07:01:24
User entered '05 Oct 2020 00:01'	System	05 Oct 2020 07:01:24

FDA-CBER-2022-1614-2894189

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894190

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894191

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	01 Oct 2020 22:22:39
User entered 'Day 5'	System	01 Oct 2020 22:22:39

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:14:49
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-05T13:29:54', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'a63e70a3-2a4a-4009-87b9-d418e8d64427'	System	05 Oct 2020 20:30:09
User entered 'None (1)'	System	05 Oct 2020 20:30:09

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:14:49
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-05T13:29:57', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'a63e70a3-2a4a-4009-87b9-d418e8d64427'	System	05 Oct 2020 20:30:09
User entered 'No (N)'	System	05 Oct 2020 20:30:09

FDA-CBER-2022-1614-2894194

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:14:49
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-05T13:30:01', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'a63e70a3-2a4a-4009-87b9-d418e8d64427'	System	05 Oct 2020 20:30:09
User entered 'No (N)'	System	05 Oct 2020 20:30:09

FDA-CBER-2022-1614-2894195

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:14:49
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-05T13:30:04', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'a63e70a3-2a4a-4009-87b9-d418e8d64427'	System	05 Oct 2020 20:30:09
User entered 'None (1)'	System	05 Oct 2020 20:30:09

FDA-CBER-2022-1614-2894196

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:14:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-05T13:30:07', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'a63e70a3-2a4a-4009-87b9-d418e8d64427'	System	05 Oct 2020 20:30:09
User entered '05 Oct 2020 13:30'	System	05 Oct 2020 20:30:09

FDA-CBER-2022-1614-2894197

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894198

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894199

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	01 Oct 2020 22:22:39
User entered 'Day 6'	System	01 Oct 2020 22:22:39

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:14:49
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

FDA-CBER-2022-1614-2894201

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:14:49
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

FDA-CBER-2022-1614-2894202

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:14:49
Please record - **REDNESS AT INJECTION SITE (in mm)**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:14:49
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

FDA-CBER-2022-1614-2894204

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:14:49
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

FDA-CBER-2022-1614-2894205

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:14:49
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

FDA-CBER-2022-1614-2894206

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:14:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

FDA-CBER-2022-1614-2894207

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894208

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894209

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	01 Oct 2020 22:22:39
User entered 'Day 7'	System	01 Oct 2020 22:22:39

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:14:49
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-07T13:15:37', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '0728f5cf-751e-49b8-8977-e9d1670ed262'	System	07 Oct 2020 20:15:53
User entered 'None (1)'	System	07 Oct 2020 20:15:53

FDA-CBER-2022-1614-2894211

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:14:49
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-07T13:15:42', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '0728f5cf-751e-49b8-8977-e9d1670ed262'	System	07 Oct 2020 20:15:53
User entered 'No (N)'	System	07 Oct 2020 20:15:53

FDA-CBER-2022-1614-2894212

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:14:49
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-07T13:15:45', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '0728f5cf-751e-49b8-8977-e9d1670ed262'	System	07 Oct 2020 20:15:53
User entered 'No (N)'	System	07 Oct 2020 20:15:53

FDA-CBER-2022-1614-2894213

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:14:49
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-07T13:15:48', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '0728f5cf-751e-49b8-8977-e9d1670ed262'	System	07 Oct 2020 20:15:53
User entered 'None (1)'	System	07 Oct 2020 20:15:53

FDA-CBER-2022-1614-2894214

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:14:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-07T13:15:51', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '0728f5cf-751e-49b8-8977-e9d1670ed262'	System	07 Oct 2020 20:15:53
User entered '07 Oct 2020 13:15'	System	07 Oct 2020 20:15:53

FDA-CBER-2022-1614-2894215

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894216

US3642086
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894217

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	01 Oct 2020 22:22:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 22:22:39

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-01T15:41:59', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '252bd778-e3b0-4621-a338-e9f20e7de2b7'	System	01 Oct 2020 22:42:19
User entered 'None (0)'	System	01 Oct 2020 22:42:19

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-01T15:42:01', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '252bd778-e3b0-4621-a338-e9f20e7de2b7'	System	01 Oct 2020 22:42:19
User entered 'None (0)'	System	01 Oct 2020 22:42:19

FDA-CBER-2022-1614-2894220

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-01T15:42:04', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '252bd778-e3b0-4621-a338-e9f20e7de2b7'	System	01 Oct 2020 22:42:19
User entered 'None (0)'	System	01 Oct 2020 22:42:19

FDA-CBER-2022-1614-2894221

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-01T15:42:06', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '252bd778-e3b0-4621-a338-e9f20e7de2b7'	System	01 Oct 2020 22:42:19
User entered 'None (0)'	System	01 Oct 2020 22:42:19

FDA-CBER-2022-1614-2894222

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-01T15:42:08', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '252bd778-e3b0-4621-a338-e9f20e7de2b7'	System	01 Oct 2020 22:42:19
User entered 'None (0)'	System	01 Oct 2020 22:42:19

FDA-CBER-2022-1614-2894223

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-01T15:42:10', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '252bd778-e3b0-4621-a338-e9f20e7de2b7'	System	01 Oct 2020 22:42:19
User entered 'None (0)'	System	01 Oct 2020 22:42:19

FDA-CBER-2022-1614-2894224

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-01T15:42:14', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '252bd778-e3b0-4621-a338-e9f20e7de2b7'	System	01 Oct 2020 22:42:19
User entered 'No (N)'	System	01 Oct 2020 22:42:19

FDA-CBER-2022-1614-2894225

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-01T15:42:16', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '252bd778-e3b0-4621-a338-e9f20e7de2b7'	System	01 Oct 2020 22:42:19
User entered '01 Oct 2020 15:42'	System	01 Oct 2020 22:42:19

FDA-CBER-2022-1614-2894226

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '01 Oct 2020 15:41'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894227

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '01 Oct 2020 18:11'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894228

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	01 Oct 2020 22:22:39
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 22:22:39

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-01T22:26:50', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'b666942e-bceb-4ce0-902f-7946fd9c0b6f'	System	02 Oct 2020 05:27:14
User entered 'None (0)'	System	02 Oct 2020 05:27:14

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-01T22:26:52', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'b666942e-bceb-4ce0-902f-7946fd9c0b6f'	System	02 Oct 2020 05:27:14
User entered 'None (0)'	System	02 Oct 2020 05:27:14

FDA-CBER-2022-1614-2894231

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-01T22:26:54', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'b666942e-bceb-4ce0-902f-7946fd9c0b6f'	System	02 Oct 2020 05:27:14
User entered 'None (0)'	System	02 Oct 2020 05:27:14

FDA-CBER-2022-1614-2894232

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-01T22:26:56', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'b666942e-bceb-4ce0-902f-7946fd9c0b6f'	System	02 Oct 2020 05:27:14
User entered 'None (0)'	System	02 Oct 2020 05:27:14

FDA-CBER-2022-1614-2894233

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-01T22:26:59', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'b666942e-bceb-4ce0-902f-7946fd9c0b6f'	System	02 Oct 2020 05:27:14
User entered 'None (0)'	System	02 Oct 2020 05:27:14

FDA-CBER-2022-1614-2894234

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-01T22:27:01', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'b666942e-bceb-4ce0-902f-7946fd9c0b6f'	System	02 Oct 2020 05:27:14
User entered 'None (0)'	System	02 Oct 2020 05:27:14

FDA-CBER-2022-1614-2894235

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-01T22:27:08', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'b666942e-bceb-4ce0-902f-7946fd9c0b6f'	System	02 Oct 2020 05:27:14
User entered 'No (N)'	System	02 Oct 2020 05:27:14

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-01T22:27:12', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'b666942e-bceb-4ce0-902f-7946fd9c0b6f'	System	02 Oct 2020 05:27:14
User entered '01 Oct 2020 22:27'	System	02 Oct 2020 05:27:14

FDA-CBER-2022-1614-2894237

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '01 Oct 2020 19:06'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894238

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894239

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	01 Oct 2020 22:22:39
User entered 'Day 2'	System	01 Oct 2020 22:22:39

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:14:49
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-02T23:07:56', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'eb31e791-ca24-4f64-bd6d-2ce3f667fea2'	System	03 Oct 2020 06:08:19
User entered 'No interference with activity (1)'	System	03 Oct 2020 06:08:19

FDA-CBER-2022-1614-2894241

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:14:49
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-02T23:08:00', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'eb31e791-ca24-4f64-bd6d-2ce3f667fea2'	System	03 Oct 2020 06:08:19
User entered 'None (0)'	System	03 Oct 2020 06:08:19

FDA-CBER-2022-1614-2894242

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:14:49
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-02T23:08:02', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'eb31e791-ca24-4f64-bd6d-2ce3f667fea2'	System	03 Oct 2020 06:08:19
User entered 'None (0)'	System	03 Oct 2020 06:08:19

FDA-CBER-2022-1614-2894243

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:14:49
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-02T23:08:07', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'eb31e791-ca24-4f64-bd6d-2ce3f667fea2'	System	03 Oct 2020 06:08:19
User entered 'None (0)'	System	03 Oct 2020 06:08:19

FDA-CBER-2022-1614-2894244

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:14:49
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-02T23:08:09', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'eb31e791-ca24-4f64-bd6d-2ce3f667fea2'	System	03 Oct 2020 06:08:19
User entered 'None (0)'	System	03 Oct 2020 06:08:19

FDA-CBER-2022-1614-2894245

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:14:49
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-02T23:08:11', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'eb31e791-ca24-4f64-bd6d-2ce3f667fea2'	System	03 Oct 2020 06:08:19
User entered 'None (0)'	System	03 Oct 2020 06:08:19

FDA-CBER-2022-1614-2894246

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:14:49
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-02T23:08:15', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'eb31e791-ca24-4f64-bd6d-2ce3f667fea2'	System	03 Oct 2020 06:08:19
User entered 'No (N)'	System	03 Oct 2020 06:08:19

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:14:49
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-02T23:08:17', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'eb31e791-ca24-4f64-bd6d-2ce3f667fea2'	System	03 Oct 2020 06:08:19
User entered '02 Oct 2020 23:08'	System	03 Oct 2020 06:08:19

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894249

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894250

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	01 Oct 2020 22:22:39
User entered 'Day 3'	System	01 Oct 2020 22:22:39

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:14:49
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-03T14:21:51', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '637cea58-ce6e-442a-8c7b-275d5e65783e'	System	03 Oct 2020 21:22:09
User entered 'None (0)'	System	03 Oct 2020 21:22:09

FDA-CBER-2022-1614-2894252

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:14:49
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-03T14:21:53', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '637cea58-ce6e-442a-8c7b-275d5e65783e'	System	03 Oct 2020 21:22:09
User entered 'None (0)'	System	03 Oct 2020 21:22:09

FDA-CBER-2022-1614-2894253

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:14:49
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-03T14:21:55', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '637cea58-ce6e-442a-8c7b-275d5e65783e'	System	03 Oct 2020 21:22:09
User entered 'None (0)'	System	03 Oct 2020 21:22:09

FDA-CBER-2022-1614-2894254

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:14:49
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-03T14:21:57', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '637cea58-ce6e-442a-8c7b-275d5e65783e'	System	03 Oct 2020 21:22:09
User entered 'None (0)'	System	03 Oct 2020 21:22:09

FDA-CBER-2022-1614-2894255

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:14:49
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-03T14:21:59', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '637cea58-ce6e-442a-8c7b-275d5e65783e'	System	03 Oct 2020 21:22:09
User entered 'None (0)'	System	03 Oct 2020 21:22:09

FDA-CBER-2022-1614-2894256

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:14:49
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-03T14:22:01', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '637cea58-ce6e-442a-8c7b-275d5e65783e'	System	03 Oct 2020 21:22:09
User entered 'None (0)'	System	03 Oct 2020 21:22:09

FDA-CBER-2022-1614-2894257

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:14:49
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-03T14:22:05', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '637cea58-ce6e-442a-8c7b-275d5e65783e'	System	03 Oct 2020 21:22:09
User entered 'No (N)'	System	03 Oct 2020 21:22:09

FDA-CBER-2022-1614-2894258

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:14:49
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-03T14:22:07', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '637cea58-ce6e-442a-8c7b-275d5e65783e'	System	03 Oct 2020 21:22:09
User entered '03 Oct 2020 14:22'	System	03 Oct 2020 21:22:09

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894260

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894261

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	01 Oct 2020 22:22:39
User entered 'Day 4'	System	01 Oct 2020 22:22:39

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:14:49
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-05T00:01:22', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '59efe704-2d16-4e30-a659-c03300c090aa'	System	05 Oct 2020 07:01:40
User entered 'None (0)'	System	05 Oct 2020 07:01:40

FDA-CBER-2022-1614-2894263

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:14:49
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-05T00:01:24', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '59efe704-2d16-4e30-a659-c03300c090aa'	System	05 Oct 2020 07:01:40
User entered 'None (0)'	System	05 Oct 2020 07:01:40

FDA-CBER-2022-1614-2894264

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:14:49
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-05T00:01:26', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '59efe704-2d16-4e30-a659-c03300c090aa'	System	05 Oct 2020 07:01:40
User entered 'None (0)'	System	05 Oct 2020 07:01:40

FDA-CBER-2022-1614-2894265

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:14:49
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-05T00:01:28', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '59efe704-2d16-4e30-a659-c03300c090aa'	System	05 Oct 2020 07:01:40
User entered 'None (0)'	System	05 Oct 2020 07:01:40

FDA-CBER-2022-1614-2894266

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:14:49
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-05T00:01:29', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '59efe704-2d16-4e30-a659-c03300c090aa'	System	05 Oct 2020 07:01:40
User entered 'None (0)'	System	05 Oct 2020 07:01:40

FDA-CBER-2022-1614-2894267

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:14:49
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-05T00:01:31', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '59efe704-2d16-4e30-a659-c03300c090aa'	System	05 Oct 2020 07:01:40
User entered 'None (0)'	System	05 Oct 2020 07:01:40

FDA-CBER-2022-1614-2894268

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:14:49
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-05T00:01:34', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '59efe704-2d16-4e30-a659-c03300c090aa'	System	05 Oct 2020 07:01:40
User entered 'No (N)'	System	05 Oct 2020 07:01:40

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:14:49
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-05T00:01:36', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '59efe704-2d16-4e30-a659-c03300c090aa'	System	05 Oct 2020 07:01:40
User entered '05 Oct 2020 00:01'	System	05 Oct 2020 07:01:40

FDA-CBER-2022-1614-2894270

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894271

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 22:22:39

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	01 Oct 2020 22:22:39
User entered 'Day 5'	System	01 Oct 2020 22:22:39

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:14:49
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-05T13:30:11', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '0c334cc9-c48a-42c0-a246-f5f2017801d6'	System	05 Oct 2020 20:30:31
User entered 'None (0)'	System	05 Oct 2020 20:30:31

FDA-CBER-2022-1614-2894274

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:14:49
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-05T13:30:13', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '0c334cc9-c48a-42c0-a246-f5f2017801d6'	System	05 Oct 2020 20:30:31
User entered 'None (0)'	System	05 Oct 2020 20:30:31

FDA-CBER-2022-1614-2894275

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:14:49
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-05T13:30:15', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '0c334cc9-c48a-42c0-a246-f5f2017801d6'	System	05 Oct 2020 20:30:31
User entered 'None (0)'	System	05 Oct 2020 20:30:31

FDA-CBER-2022-1614-2894276

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:14:49
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-05T13:30:17', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '0c334cc9-c48a-42c0-a246-f5f2017801d6'	System	05 Oct 2020 20:30:31
User entered 'None (0)'	System	05 Oct 2020 20:30:31

FDA-CBER-2022-1614-2894277

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:14:49
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-05T13:30:18', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '0c334cc9-c48a-42c0-a246-f5f2017801d6'	System	05 Oct 2020 20:30:31
User entered 'None (0)'	System	05 Oct 2020 20:30:31

FDA-CBER-2022-1614-2894278

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:14:49
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-05T13:30:20', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '0c334cc9-c48a-42c0-a246-f5f2017801d6'	System	05 Oct 2020 20:30:31
User entered 'None (0)'	System	05 Oct 2020 20:30:31

FDA-CBER-2022-1614-2894279

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:14:49
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-05T13:30:24', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '0c334cc9-c48a-42c0-a246-f5f2017801d6'	System	05 Oct 2020 20:30:31
User entered 'No (N)'	System	05 Oct 2020 20:30:31

FDA-CBER-2022-1614-2894280

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:14:49
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-05T13:30:27', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '0c334cc9-c48a-42c0-a246-f5f2017801d6'	System	05 Oct 2020 20:30:31
User entered '05 Oct 2020 13:30'	System	05 Oct 2020 20:30:31

FDA-CBER-2022-1614-2894281

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894282

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894283

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	01 Oct 2020 22:22:39
User entered 'Day 6'	System	01 Oct 2020 22:22:39

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:14:49
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

FDA-CBER-2022-1614-2894285

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:14:49
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

FDA-CBER-2022-1614-2894286

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:14:49
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

FDA-CBER-2022-1614-2894287

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:14:49
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:14:49
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

FDA-CBER-2022-1614-2894289

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:14:49
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

FDA-CBER-2022-1614-2894290

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:14:49
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:14:49
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23

FDA-CBER-2022-1614-2894292

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894293

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894294

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	01 Oct 2020 22:22:39
User entered 'Day 7'	System	01 Oct 2020 22:22:39

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:14:49
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-07T13:15:54', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'fae54f7d-7bc5-48f8-8e40-207d5248efad'	System	07 Oct 2020 20:16:14
User entered 'None (0)'	System	07 Oct 2020 20:16:14

FDA-CBER-2022-1614-2894296

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:14:49
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-07T13:15:56', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'fae54f7d-7bc5-48f8-8e40-207d5248efad'	System	07 Oct 2020 20:16:14
User entered 'None (0)'	System	07 Oct 2020 20:16:14

FDA-CBER-2022-1614-2894297

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:14:49
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-07T13:15:58', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'fae54f7d-7bc5-48f8-8e40-207d5248efad'	System	07 Oct 2020 20:16:14
User entered 'None (0)'	System	07 Oct 2020 20:16:14

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:14:49
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-07T13:16:02', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'fae54f7d-7bc5-48f8-8e40-207d5248efad'	System	07 Oct 2020 20:16:14
User entered 'None (0)'	System	07 Oct 2020 20:16:14

FDA-CBER-2022-1614-2894299

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:14:49
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-07T13:16:04', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'fae54f7d-7bc5-48f8-8e40-207d5248efad'	System	07 Oct 2020 20:16:14
User entered 'None (0)'	System	07 Oct 2020 20:16:14

FDA-CBER-2022-1614-2894300

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:14:49
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-07T13:16:06', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'fae54f7d-7bc5-48f8-8e40-207d5248efad'	System	07 Oct 2020 20:16:14
User entered 'None (0)'	System	07 Oct 2020 20:16:14

FDA-CBER-2022-1614-2894301

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:14:49
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-07T13:16:10', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'fae54f7d-7bc5-48f8-8e40-207d5248efad'	System	07 Oct 2020 20:16:14
User entered 'No (N)'	System	07 Oct 2020 20:16:14

FDA-CBER-2022-1614-2894302

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:14:49
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (969FE349-5F3D-433B-A36B-BF51C2A69346)', Time: '2020-10-07T13:16:12', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'fae54f7d-7bc5-48f8-8e40-207d5248efad'	System	07 Oct 2020 20:16:14
User entered '07 Oct 2020 13:16'	System	07 Oct 2020 20:16:14

FDA-CBER-2022-1614-2894303

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:14:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894304

US3642086
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:14:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 22:22:39

FDA-CBER-2022-1614-2894305

US3642086
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:44:59
User entered 'Yes (Y)'	Nancy Tang (b) (4)	09 Oct 2020 00:34:32

US3642086
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:44:59
User entered '08 Oct 2020'	Nancy Tang (b) (4)	09 Oct 2020 00:34:32

US3642086
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:44:59
User entered 'Contact Made (CONTACT MADE)'	Nancy Tang (b) (4)	09 Oct 2020 00:34:32

US3642086
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:44:59
User entered empty.	Nancy Tang (b) (4)	09 Oct 2020 00:34:32

US3642086
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:14:49
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:46:19
User entered 'Yes (Y)'	Nancy Tang (b) (4)	09 Oct 2020 00:34:36

US3642086
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:14:49
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered '1'	System	09 Oct 2020 00:34:36

FDA-CBER-2022-1614-2894311

US3642086
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 21:53:48
User entered 'Yes (Y)'	Lindsey Woronicz (b) (4)	16 Oct 2020 18:27:31

US3642086
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 21:53:48
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	26 Oct 2020 18:34:50
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	26 Oct 2020 18:34:50
User entered '16 Oct 2020' reason for change: Data Entry Error	Lindsey Woronicz (b) (4)	26 Oct 2020 18:34:50
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	26 Oct 2020 18:14:17
User entered '24 Oct 2020' reason for change: New Information	Lindsey Woronicz (b) (4)	26 Oct 2020 18:14:17
User entered '15 Oct 2020' reason for change: Data Entry Error	Nancy Tang (b) (4)	17 Oct 2020 02:34:58
User entered '16 Oct 2020'	Lindsey Woronicz (b) (4)	16 Oct 2020 18:27:31

US3642086
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 21:53:48
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	Lindsey Woronicz (b) (4)	26 Oct 2020 18:34:50
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	Lindsey Woronicz (b) (4)	26 Oct 2020 18:14:17
User entered 'Contact Not Made (CONTACT NOT MADE)'	Lindsey Woronicz (b) (4)	16 Oct 2020 18:27:31

US3642086
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 21:53:48
User entered 'ATTEMPT 1 15/10/2020 5:00PM ATTEMPT #2 16/10/2020 AT 11:25 AM ATTEMPT #3 16/10/2020 4:19 PM' reason for change: Data Entry Error	Lindsey Woronicz (b) (4)	26 Oct 2020 18:34:50
User entered 'ATTEMPT 1 15/10/2020 5:00PM ATTEMPT #2 16/10/2020 AT 11:25 AM ATTEMPT #3 16/10/2020 4:19 PM EMAIL SENT -CONTACT MADE VIA EMAIL 24/OCT/2020 4:16 PM-' reason for change: Data Entry Error	Lindsey Woronicz (b) (4)	26 Oct 2020 18:14:17
User entered 'ATTEMPT 1 15/10/2020 5:00PM ATTEMPT #2 16/10/2020 AT 11:25 AM ATTEMPT #3 16/10/2020 4:19 PM' reason for change: Data Entry Error	Nancy Tang (b) (4)	17 Oct 2020 02:33:27
User entered 'ATTEMPT #2 16/10/2020 AT 11:25 AM ATTEMPT #3 16/10/2020 4:19 PM' reason for change: Data Entry Error	Lindsey Woronicz (b) (4)	16 Oct 2020 23:23:45
User entered 'ATTEMPT #2 16/10/2020 AT 11:25 AM'	Lindsey Woronicz (b) (4)	16 Oct 2020 18:27:31

FDA-CBER-2022-1614-2894315

US3642086
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:14:49
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:53:20
User entered 'Yes (Y)'	Lindsey Woronicz (b) (4)	16 Oct 2020 18:27:40

US3642086
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:14:49
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered '1'	System	16 Oct 2020 18:27:40

FDA-CBER-2022-1614-2894317

US3642086
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:54:15
User entered 'Yes (Y)'	Nancy Tang (b) (4)	26 Oct 2020 18:31:21

US3642086
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:54:15
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		06 Nov 2020 11:58:40
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Call made late' (Site from System).	Benjamin Hull (b) (4) (b) (4)	05 Nov 2020 18:13:46
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	26 Oct 2020 18:31:21
User entered '26 Oct 2020'	Nancy Tang (b) (4)	26 Oct 2020 18:31:21

US3642086
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:54:15
User entered 'Contact Made (CONTACT MADE)'	Nancy Tang (b) (4)	26 Oct 2020 18:31:21

US3642086
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:54:15
User entered '3 ATTEMPTS MADE UNSUCCESSFUL. SUBJECT CALLED BACK OUT OF WINDOW ON 26OCT2020. ATTEMPT1 23OCT2020 10:07AM ATTEMPT2 23OCT2020 16:00PM ATTEMPT 3 24OCT2020 09:43AM' reason for change: New Information	Nancy Tang (b) (4)	26 Oct 2020 18:32:58
User entered empty.	Nancy Tang (b) (4)	26 Oct 2020 18:31:21

FDA-CBER-2022-1614-2894321

US3642086
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:14:49
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:32
User entered 'Yes (Y)'	Nancy Tang (b) (4)	26 Oct 2020 18:33:03

US3642086
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:14:49
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered '1'	System	26 Oct 2020 18:33:03

US3642086
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:58:27
User entered 'Yes (Y)'	Son Do (b) (4)	04 Nov 2020 16:12:53

FDA-CBER-2022-1614-2894324

US3642086
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:58:27
User entered '02 Nov 2020'	Son Do (b) (4)	04 Nov 2020 16:12:53

US3642086
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:58:27
User entered 'Clinic (Clinic)'	Son Do (b) (4)	04 Nov 2020 16:12:53

FDA-CBER-2022-1614-2894326

US3642086
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered 'VISIT3'	System	04 Nov 2020 16:12:53

FDA-CBER-2022-1614-2894327

US3642086
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:58:53
User entered 'Yes (Y)'	Son Do (b) (4)	04 Nov 2020 16:13:14

US3642086
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:58:53
User entered '02 Nov 2020'	Son Do (b) (4)	04 Nov 2020 16:13:14

FDA-CBER-2022-1614-2894329

US3642086
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:58:53
User entered '13:50'	Son Do (b) (4)	04 Nov 2020 16:13:14

FDA-CBER-2022-1614-2894330

US3642086
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered '02 Nov 2020 13:50'	System	04 Nov 2020 16:13:14

FDA-CBER-2022-1614-2894331

US3642086
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:58:53
User entered '97.7' F	Son Do (b) (4)	04 Nov 2020 16:13:14

US3642086
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:58:53
User entered 'Oral (Oral)'	Son Do (b) (4)	04 Nov 2020 16:13:14

FDA-CBER-2022-1614-2894333

US3642086
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:58:53
User entered empty.	Son Do (b) (4)	04 Nov 2020 16:13:14

US3642086
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:58:53
User entered '80'	Son Do (b) (4)	04 Nov 2020 16:13:14

FDA-CBER-2022-1614-2894335

US3642086
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered 'bpm'	System	04 Nov 2020 16:13:14

FDA-CBER-2022-1614-2894336

US3642086
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:58:53
User entered '16'	Son Do (b) (4)	04 Nov 2020 16:13:14

FDA-CBER-2022-1614-2894337

US3642086
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered 'breaths/min'	System	04 Nov 2020 16:13:14

FDA-CBER-2022-1614-2894338

US3642086
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:58:53
User entered '134'	Son Do (b) (4)	04 Nov 2020 16:13:14

FDA-CBER-2022-1614-2894339

US3642086
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered 'mmHg'	System	04 Nov 2020 16:13:14

FDA-CBER-2022-1614-2894340

US3642086
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:58:53
User entered '78'	Son Do (b) (4)	04 Nov 2020 16:13:14

FDA-CBER-2022-1614-2894341

US3642086
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered 'mmHg'	System	04 Nov 2020 16:13:14

FDA-CBER-2022-1614-2894342

US3642086
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27

FDA-CBER-2022-1614-2894343

US3642086
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27

FDA-CBER-2022-1614-2894344

US3642086
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:14:49
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:59:02
User entered 'No (N)'	Son Do (b) (4)	04 Nov 2020 16:13:20

US3642086
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:14:49
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:59:02
User entered empty.	Son Do (b) (4)	04 Nov 2020 16:13:20

FDA-CBER-2022-1614-2894346

US3642086
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:14:49
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:59:14
User entered 'Yes (Y)'	Son Do (b) (4)	04 Nov 2020 16:13:38

FDA-CBER-2022-1614-2894347

US3642086
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:14:49
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:59:14
User entered '02 Nov 2020'	Son Do (b) (4)	04 Nov 2020 16:13:38

FDA-CBER-2022-1614-2894348

US3642086
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:14:49
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:59:14
User entered '14:05'	Son Do (b) (4)	04 Nov 2020 16:13:38

US3642086
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:14:49
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered '02 Nov 2020 14:05'	System	04 Nov 2020 16:13:38

US3642086
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:14:49
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:59:17
User entered 'Yes (Y)'	Son Do (b) (4)	04 Nov 2020 16:13:44

FDA-CBER-2022-1614-2894351

US3642086
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:14:49
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered '1'	System	04 Nov 2020 16:13:44

FDA-CBER-2022-1614-2894352

US3642086
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	02 Sep 2020 23:51:18
User entered 'Day 64'	System	02 Sep 2020 23:51:18

US3642086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:49

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)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-11-03T16:21:35', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '81238591-7b3b-4bad-8b0a-dc9cf0719df9'	System	04 Nov 2020 00:21:44
User entered 'No (N)'	System	04 Nov 2020 00:21:44

US3642086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:49

Have you been exposed to someone with 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)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-11-03T16:21:38', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '81238591-7b3b-4bad-8b0a-dc9cf0719df9'	System	04 Nov 2020 00:21:44
User entered 'No (N)'	System	04 Nov 2020 00:21:44

US3642086
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-11-03T16:21:42', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '81238591-7b3b-4bad-8b0a-dc9cf0719df9'	System	04 Nov 2020 00:21:44
User entered '03 Nov 2020 16:21:42'	System	04 Nov 2020 00:21:44

US3642086
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	02 Sep 2020 23:51:18
User entered '02 Nov 2020 00:01'	System	02 Sep 2020 23:51:18

US3642086
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	02 Sep 2020 23:51:18
User entered '06 Nov 2020 23:59'	System	02 Sep 2020 23:51:18

US3642086
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	02 Sep 2020 23:51:18
User entered 'Day 71'	System	02 Sep 2020 23:51:18

US3642086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:49

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)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-11-11T00:07:39', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'd6ae7f0c-847f-4a69-910d-70e68a8d0611'	System	11 Nov 2020 08:07:55
User entered 'No (N)'	System	11 Nov 2020 08:07:55

US3642086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:49

Have you been exposed to someone with 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)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-11-11T00:07:48', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'd6ae7f0c-847f-4a69-910d-70e68a8d0611'	System	11 Nov 2020 08:07:55
User entered 'No (N)'	System	11 Nov 2020 08:07:55

US3642086
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-11-11T00:07:51', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'd6ae7f0c-847f-4a69-910d-70e68a8d0611'	System	11 Nov 2020 08:07:55
User entered '11 Nov 2020 00:07:51'	System	11 Nov 2020 08:07:55

US3642086
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	02 Sep 2020 23:51:18
User entered '09 Nov 2020 00:01'	System	02 Sep 2020 23:51:18

US3642086
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:23
Data entry locked.	System	02 Sep 2020 23:51:18
User entered '13 Nov 2020 23:59'	System	02 Sep 2020 23:51:18

US3642086
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:21:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:01:05
Data entry locked.	System	02 Sep 2020 23:51:18
User entered 'Day 78'	System	02 Sep 2020 23:51:18

US3642086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:49

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)	25 Apr 2021 12:21:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:01:05

US3642086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:49

Have you been exposed to someone with 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)	25 Apr 2021 12:21:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:01:05

US3642086
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Please 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)	25 Apr 2021 12:21:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:01:05

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US3642086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:49

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)	25 Apr 2021 12:21:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:01:05

US3642086
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:21:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:01:05

US3642086
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:21:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:01:05

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US3642086
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:21:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:01:05

FDA-CBER-2022-1614-2894372

US3642086
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:21:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:01:05

US3642086
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:21:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:01:05

US3642086
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:21:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:01:05

US3642086
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:21:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:01:05

US3642086
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:21:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:01:05

US3642086
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:21:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:01:05

US3642086
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:21:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:01:05

US3642086
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:21:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:01:05

US3642086
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:21:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:01:05

US3642086
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:21:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:01:05

US3642086
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:21:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:01:05

US3642086
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:21:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:01:05

US3642086
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:21:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:01:05

US3642086
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:21:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:01:05

FDA-CBER-2022-1614-2894386

US3642086
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Please 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)	25 Apr 2021 12:21:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:01:05

FDA-CBER-2022-1614-2894387

US3642086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:49

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)	25 Apr 2021 12:21:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:01:05

US3642086
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Please 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)	25 Apr 2021 12:21:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:01:05

US3642086
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:21:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:01:05

US3642086
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:21:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:01:05
Data entry locked.	System	02 Sep 2020 23:51:18
User entered '16 Nov 2020 00:01'	System	02 Sep 2020 23:51:18

US3642086
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:21:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:01:05
Data entry locked.	System	02 Sep 2020 23:51:18
User entered '20 Nov 2020 23:59'	System	02 Sep 2020 23:51:18

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 03:01:05

US3642086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:49

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 (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-11-23T20:29:42', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'f921cd37-de81-4697-b67a-b2145e421109'	System	24 Nov 2020 04:29:55
User entered 'No (N)'	System	24 Nov 2020 04:29:55

US3642086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:49

Have you been exposed to someone with 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 (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-11-23T20:29:46', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'f921cd37-de81-4697-b67a-b2145e421109'	System	24 Nov 2020 04:29:55
User entered 'No (N)'	System	24 Nov 2020 04:29:55

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-11-23T20:29:49', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'f921cd37-de81-4697-b67a-b2145e421109'	System	24 Nov 2020 04:29:55
User entered '23 Nov 2020 20:29:49'	System	24 Nov 2020 04:29:55

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 03:01:05

US3642086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:49

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 (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-11-30T18:01:29', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '5c70693e-6cd0-4298-82c6-d4ae2229eb10'	System	01 Dec 2020 02:01:41
User entered 'No (N)'	System	01 Dec 2020 02:01:41

US3642086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:49

Have you been exposed to someone with 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 (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-11-30T18:01:32', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '5c70693e-6cd0-4298-82c6-d4ae2229eb10'	System	01 Dec 2020 02:01:41
User entered 'No (N)'	System	01 Dec 2020 02:01:41

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-11-30T18:01:35', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '5c70693e-6cd0-4298-82c6-d4ae2229eb10'	System	01 Dec 2020 02:01:41
User entered '30 Nov 2020 18:01:35'	System	01 Dec 2020 02:01:41

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 03:01:05

US3642086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:49

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 (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-12-07T15:36:12', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'd36a22c2-dc1e-463b-ba5b-2c1fdd013c9e'	System	07 Dec 2020 23:36:22
User entered 'No (N)'	System	07 Dec 2020 23:36:22

US3642086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:49

Have you been exposed to someone with 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 (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-12-07T15:36:16', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'd36a22c2-dc1e-463b-ba5b-2c1fdd013c9e'	System	07 Dec 2020 23:36:22
User entered 'No (N)'	System	07 Dec 2020 23:36:22

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-12-07T15:36:20', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'd36a22c2-dc1e-463b-ba5b-2c1fdd013c9e'	System	07 Dec 2020 23:36:22
User entered '07 Dec 2020 15:36:20'	System	07 Dec 2020 23:36:22

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 03:01:05

US3642086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:49

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 (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-12-20T15:51:54', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '24e5d27d-9b1c-4e4a-9adf-a22edc6eaa64'	System	20 Dec 2020 23:52:57
User entered 'Yes (Y)'	System	20 Dec 2020 23:52:57

US3642086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:49

Have you been exposed to someone with 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 (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-12-20T15:52:01', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '24e5d27d-9b1c-4e4a-9adf-a22edc6eaa64'	System	20 Dec 2020 23:52:57
User entered 'Yes (Y)'	System	20 Dec 2020 23:52:57

US3642086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:49

Please 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 (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-12-20T15:52:10', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '24e5d27d-9b1c-4e4a-9adf-a22edc6eaa64'	System	20 Dec 2020 23:52:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Dec 2020 23:52:57

US3642086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:49

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 (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-12-20T15:52:18', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '24e5d27d-9b1c-4e4a-9adf-a22edc6eaa64'	System	20 Dec 2020 23:52:57
User entered 'Yes (Y)'	System	20 Dec 2020 23:52:57

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-12-20T15:52:31', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '24e5d27d-9b1c-4e4a-9adf-a22edc6eaa64'	System	20 Dec 2020 23:52:57
User entered '0'	System	20 Dec 2020 23:52:57

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Chills

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-12-20T15:52:31', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '24e5d27d-9b1c-4e4a-9adf-a22edc6eaa64'	System	20 Dec 2020 23:52:57
User entered '1'	System	20 Dec 2020 23:52:57

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Cough

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-12-20T15:52:31', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '24e5d27d-9b1c-4e4a-9adf-a22edc6eaa64'	System	20 Dec 2020 23:52:57
User entered '0'	System	20 Dec 2020 23:52:57

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Shortness of breath

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-12-20T15:52:31', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '24e5d27d-9b1c-4e4a-9adf-a22edc6eaa64'	System	20 Dec 2020 23:52:57
User entered '0'	System	20 Dec 2020 23:52:57

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Difficulty breathing

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-12-20T15:52:31', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '24e5d27d-9b1c-4e4a-9adf-a22edc6eaa64'	System	20 Dec 2020 23:52:57
User entered '0'	System	20 Dec 2020 23:52:57

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Fatigue

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-12-20T15:52:31', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '24e5d27d-9b1c-4e4a-9adf-a22edc6eaa64'	System	20 Dec 2020 23:52:57
User entered '1'	System	20 Dec 2020 23:52:57

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Muscle aches

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-12-20T15:52:31', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '24e5d27d-9b1c-4e4a-9adf-a22edc6eaa64'	System	20 Dec 2020 23:52:57
User entered '1'	System	20 Dec 2020 23:52:57

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Body aches

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-12-20T15:52:31', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '24e5d27d-9b1c-4e4a-9adf-a22edc6eaa64'	System	20 Dec 2020 23:52:57
User entered '1'	System	20 Dec 2020 23:52:57

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Headache

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-12-20T15:52:31', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '24e5d27d-9b1c-4e4a-9adf-a22edc6eaa64'	System	20 Dec 2020 23:52:57
User entered '1'	System	20 Dec 2020 23:52:57

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
New loss of taste

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-12-20T15:52:31', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '24e5d27d-9b1c-4e4a-9adf-a22edc6eaa64'	System	20 Dec 2020 23:52:57
User entered '0'	System	20 Dec 2020 23:52:57

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
New loss of smell

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-12-20T15:52:31', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '24e5d27d-9b1c-4e4a-9adf-a22edc6eaa64'	System	20 Dec 2020 23:52:57
User entered '0'	System	20 Dec 2020 23:52:57

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Sore throat

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-12-20T15:52:31', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '24e5d27d-9b1c-4e4a-9adf-a22edc6eaa64'	System	20 Dec 2020 23:52:57
User entered '0'	System	20 Dec 2020 23:52:57

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Congestion

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-12-20T15:52:31', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '24e5d27d-9b1c-4e4a-9adf-a22edc6eaa64'	System	20 Dec 2020 23:52:57
User entered '0'	System	20 Dec 2020 23:52:57

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Runny nose

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-12-20T15:52:31', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '24e5d27d-9b1c-4e4a-9adf-a22edc6eaa64'	System	20 Dec 2020 23:52:57
User entered '0'	System	20 Dec 2020 23:52:57

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Nausea

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-12-20T15:52:31', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '24e5d27d-9b1c-4e4a-9adf-a22edc6eaa64'	System	20 Dec 2020 23:52:57
User entered '0'	System	20 Dec 2020 23:52:57

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Vomiting

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-12-20T15:52:31', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '24e5d27d-9b1c-4e4a-9adf-a22edc6eaa64'	System	20 Dec 2020 23:52:57
User entered '0'	System	20 Dec 2020 23:52:57

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Diarrhea

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-12-20T15:52:31', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '24e5d27d-9b1c-4e4a-9adf-a22edc6eaa64'	System	20 Dec 2020 23:52:57
User entered '1'	System	20 Dec 2020 23:52:57

US3642086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:49

Please 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 (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-12-20T15:52:35', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '24e5d27d-9b1c-4e4a-9adf-a22edc6eaa64'	System	20 Dec 2020 23:52:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Dec 2020 23:52:57

US3642086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:49

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 (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-12-20T15:52:41', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '24e5d27d-9b1c-4e4a-9adf-a22edc6eaa64'	System	20 Dec 2020 23:52:57
User entered 'Yes (Y)'	System	20 Dec 2020 23:52:57

US3642086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:49

Please 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 (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-12-20T15:52:44', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '24e5d27d-9b1c-4e4a-9adf-a22edc6eaa64'	System	20 Dec 2020 23:52:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Dec 2020 23:52:57

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2020-12-20T15:52:48', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '24e5d27d-9b1c-4e4a-9adf-a22edc6eaa64'	System	20 Dec 2020 23:52:57
User entered '20 Dec 2020 15:52:48'	System	20 Dec 2020 23:52:57

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 03:01:05

US3642086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:49

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 (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2021-01-31T21:21:49', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '204ee611-8e1e-473b-8ca0-9d0b1c5b9fcf'	System	01 Feb 2021 05:22:04
User entered 'No (N)'	System	01 Feb 2021 05:22:04

US3642086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:49

Have you been exposed to someone with 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 (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2021-01-31T21:21:53', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '204ee611-8e1e-473b-8ca0-9d0b1c5b9fcf'	System	01 Feb 2021 05:22:04
User entered 'No (N)'	System	01 Feb 2021 05:22:04

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2021-01-31T21:21:57', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '204ee611-8e1e-473b-8ca0-9d0b1c5b9fcf'	System	01 Feb 2021 05:22:04
User entered '31 Jan 2021 21:21:57'	System	01 Feb 2021 05:22:04

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 03:01:05

US3642086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:49

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 (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2021-02-09T17:34:21', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '74357691-ed4a-40f8-a32d-25f02fbdbb3e'	System	10 Feb 2021 01:34:33
User entered 'No (N)'	System	10 Feb 2021 01:34:33

US3642086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:49

Have you been exposed to someone with 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 (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2021-02-09T17:34:27', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '74357691-ed4a-40f8-a32d-25f02fbdbb3e'	System	10 Feb 2021 01:34:33
User entered 'No (N)'	System	10 Feb 2021 01:34:33

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2021-02-09T17:34:30', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '74357691-ed4a-40f8-a32d-25f02fbdbb3e'	System	10 Feb 2021 01:34:33
User entered '09 Feb 2021 17:34:30'	System	10 Feb 2021 01:34:33

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 03:01:05

US3642086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:49

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 (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2021-02-16T12:41:00', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '959ceb08-601c-4147-81f6-90c2e5d95eba'	System	16 Feb 2021 20:41:11
User entered 'No (N)'	System	16 Feb 2021 20:41:11

US3642086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:49

Have you been exposed to someone with 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 (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2021-02-16T12:41:04', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '959ceb08-601c-4147-81f6-90c2e5d95eba'	System	16 Feb 2021 20:41:11
User entered 'No (N)'	System	16 Feb 2021 20:41:11

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2021-02-16T12:41:07', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '959ceb08-601c-4147-81f6-90c2e5d95eba'	System	16 Feb 2021 20:41:11
User entered '16 Feb 2021 12:41:07'	System	16 Feb 2021 20:41:11

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 03:01:05

US3642086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:49

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 (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2021-03-23T17:00:49-07:00', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'e9a076e2-8b37-4fa7-af04-f32636301530'	System	24 Mar 2021 00:01:37
User entered 'No (N)'	System	24 Mar 2021 00:01:37

US3642086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:49

Have you been exposed to someone with 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 (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2021-03-23T17:00:55-07:00', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'e9a076e2-8b37-4fa7-af04-f32636301530'	System	24 Mar 2021 00:01:37
User entered 'No (N)'	System	24 Mar 2021 00:01:37

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2021-03-23T17:00:58-07:00', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'e9a076e2-8b37-4fa7-af04-f32636301530'	System	24 Mar 2021 00:01:37
User entered '23 Mar 2021 17:00:58'	System	24 Mar 2021 00:01:37

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 03:01:05

US3642086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:49

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 (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2021-03-29T15:53:52-07:00', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '1e74b143-0682-4f39-8fa3-ac56aef14315'	System	29 Mar 2021 22:54:01
User entered 'No (N)'	System	29 Mar 2021 22:54:01

US3642086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:49

Have you been exposed to someone with 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 (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2021-03-29T15:53:55-07:00', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '1e74b143-0682-4f39-8fa3-ac56aef14315'	System	29 Mar 2021 22:54:01
User entered 'No (N)'	System	29 Mar 2021 22:54:01

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2021-03-29T15:53:58-07:00', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '1e74b143-0682-4f39-8fa3-ac56aef14315'	System	29 Mar 2021 22:54:01
User entered '29 Mar 2021 15:53:58'	System	29 Mar 2021 22:54:01

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 03:01:05

US3642086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:49

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 (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2021-04-06T13:05:29-07:00', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '0eadd467-f1fb-4417-a3fe-84d64ae08713'	System	06 Apr 2021 20:05:38
User entered 'No (N)'	System	06 Apr 2021 20:05:38

US3642086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:49

Have you been exposed to someone with 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 (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2021-04-06T13:05:32-07:00', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '0eadd467-f1fb-4417-a3fe-84d64ae08713'	System	06 Apr 2021 20:05:38
User entered 'No (N)'	System	06 Apr 2021 20:05:38

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2021-04-06T13:05:34-07:00', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '0eadd467-f1fb-4417-a3fe-84d64ae08713'	System	06 Apr 2021 20:05:38
User entered '06 Apr 2021 13:05:34'	System	06 Apr 2021 20:05:38

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 03:01:05

US3642086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:49

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 (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2021-04-11T16:13:59-07:00', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '6bab7a1c-7768-475d-a805-691256235b63'	System	11 Apr 2021 23:14:10
User entered 'No (N)'	System	11 Apr 2021 23:14:10

US3642086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:49

Have you been exposed to someone with 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 (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2021-04-11T16:14:02-07:00', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '6bab7a1c-7768-475d-a805-691256235b63'	System	11 Apr 2021 23:14:10
User entered 'No (N)'	System	11 Apr 2021 23:14:10

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2021-04-11T16:14:05-07:00', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '6bab7a1c-7768-475d-a805-691256235b63'	System	11 Apr 2021 23:14:10
User entered '11 Apr 2021 16:14:05'	System	11 Apr 2021 23:14:10

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 03:01:05

US3642086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:49

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 (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2021-04-19T13:58:01-07:00', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '42a72134-50e6-4873-b627-7c2d17e7a72d'	System	19 Apr 2021 20:58:10
User entered 'No (N)'	System	19 Apr 2021 20:58:10

US3642086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:49

Have you been exposed to someone with 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 (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2021-04-19T13:58:04-07:00', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '42a72134-50e6-4873-b627-7c2d17e7a72d'	System	19 Apr 2021 20:58:10
User entered 'No (N)'	System	19 Apr 2021 20:58:10

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2021-04-19T13:58:06-07:00', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '42a72134-50e6-4873-b627-7c2d17e7a72d'	System	19 Apr 2021 20:58:10
User entered '19 Apr 2021 13:58:06'	System	19 Apr 2021 20:58:10

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 03:01:05

US3642086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:49

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 (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2021-04-27T17:49:22-07:00', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '11347f9d-093c-430d-a151-46bd4f6d48ed'	System	29 Apr 2021 01:45:20
User entered 'No (N)'	System	29 Apr 2021 01:45:20

US3642086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:49

Have you been exposed to someone with 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 (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2021-04-27T17:49:25-07:00', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '11347f9d-093c-430d-a151-46bd4f6d48ed'	System	29 Apr 2021 01:45:20
User entered 'No (N)'	System	29 Apr 2021 01:45:20

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2021-04-27T17:49:28-07:00', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: '11347f9d-093c-430d-a151-46bd4f6d48ed'	System	29 Apr 2021 01:45:20
User entered '27 Apr 2021 17:49:28'	System	29 Apr 2021 01:45:20

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 03:01:05

US3642086
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:14:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:01:05
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 03:01:05

US3642086

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:14:49

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)	25 Apr 2021 12:21:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2021-03-03T17:17:45-08:00', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'efbe8c15-60d8-4baf-94cc-dad558673e42'	System	04 Mar 2021 01:17:51
User entered 'No (N)'	System	04 Mar 2021 01:17:51

US3642086
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary (1)
Generated On: 10 Jun 2021 09:14:49
Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:21:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53FA1079-2733-4B7C-822D-C2B99B9870B9)', Time: '2021-03-03T17:17:49-08:00', User OID: 'PatientReportedOutcome (US3642086)', ODM File OID: 'efbe8c15-60d8-4baf-94cc-dad558673e42'	System	04 Mar 2021 01:17:51
User entered '03 Mar 2021 17:17:49'	System	04 Mar 2021 01:17:51

FDA-CBER-2022-1614-2894764

US3642086
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 19:31:05
User entered 'Yes (Y)'	Jennifer Morales (b) (4) (b) (4)	30 Nov 2020 18:28:41

US3642086
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 19:31:05
User entered '28 Nov 2020'	Jennifer Morales (b) (4) (b) (4)	30 Nov 2020 18:28:41

US3642086
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 19:31:05
User entered 'Contact Made (CONTACT MADE)'	Jennifer Morales (b) (4) (b) (4)	30 Nov 2020 18:28:41

US3642086
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 19:31:05
User entered empty.	Jennifer Morales (b) (4) (b) (4)	30 Nov 2020 18:28:41

US3642086
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:14:49
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 19:31:11
User entered 'Yes (Y)'	Jennifer Morales (b) (4) (b) (4)	30 Nov 2020 18:28:47

US3642086
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:14:49
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:18:27
User entered '1'	System	30 Nov 2020 18:28:47

FDA-CBER-2022-1614-2894770

US3642086
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:19:14
DataPoint Verified.		23 Mar 2021 17:43:24
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered 'Yes (Y)'	Nancy Tang (b) (4)	07 Jan 2021 00:59:41

FDA-CBER-2022-1614-2894771

US3642086
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:19:14
DataPoint Verified.		23 Mar 2021 17:43:24
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered '29 Dec 2020'	Nancy Tang (b) (4)	07 Jan 2021 00:59:41

US3642086
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:19:14
DataPoint Verified.		23 Mar 2021 17:43:24
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered 'Contact Made (CONTACT MADE)'	Nancy Tang (b) (4)	07 Jan 2021 00:59:41

FDA-CBER-2022-1614-2894773

US3642086
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:19:14
DataPoint Verified.		23 Mar 2021 17:43:24
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered empty.	Nancy Tang (b) (4)	07 Jan 2021 00:59:41

FDA-CBER-2022-1614-2894774

US3642086
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:14:49
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:19:14
DataPoint Verified.		23 Mar 2021 17:43:49
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered 'Yes (Y)'	Nancy Tang (b) (4)	07 Jan 2021 00:59:45

US3642086
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:14:49
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:19:14
User entered '1'	System	07 Jan 2021 00:59:45

US3642086
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:19:14
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	26 Mar 2021 21:17:34
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 17:46:06
Signature has been broken.	Megan Loughran (b) (4) (b) (4)	22 Mar 2021 23:06:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	22 Mar 2021 23:06:53
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered 'No (N)'	Lindsey Woronicz (b) (4)	03 Feb 2021 00:23:50

FDA-CBER-2022-1614-2894777

US3642086
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:19:14
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	26 Mar 2021 21:17:34
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 17:46:06
Signature has been broken.	Megan Loughran (b) (4) (b) (4)	22 Mar 2021 23:06:53
User entered '29 Jan 2021' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	22 Mar 2021 23:06:53
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered empty.	Lindsey Woronicz (b) (4)	03 Feb 2021 00:23:50

US3642086
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:19:14
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:17:34
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 17:46:06
Signature has been broken.	Megan Loughran (b) (4)	22 Mar 2021 23:06:53
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	Megan Loughran (b) (4)	22 Mar 2021 23:06:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
User entered empty.	Lindsey Woronicz (b) (4)	03 Feb 2021 00:23:50

US3642086
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:19:14
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	26 Mar 2021 21:17:34
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 17:46:06
Signature has been broken.	Megan Loughran (b) (4) (b) (4)	22 Mar 2021 23:06:53
User entered 'unable to reach pt after multiple attempts on 1/29/21, 2/1/21, 2/2/21, email sent.' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	22 Mar 2021 23:06:53
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered empty.	Lindsey Woronicz (b) (4)	03 Feb 2021 00:23:50

US3642086
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:14:49
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:19:14
DataPoint Verified.		23 Mar 2021 17:46:09
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered 'Yes (Y)'	Lindsey Woronicz (b) (4)	03 Feb 2021 00:23:55

FDA-CBER-2022-1614-2894781

US3642086
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:14:49
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:19:14
User entered '1'	System	03 Feb 2021 00:23:55

FDA-CBER-2022-1614-2894782

US3642086
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:19:14
DataPoint Verified.		23 Mar 2021 17:50:46
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered 'Yes (Y)'	Jennifer Morales (b) (4) (b) (4)	04 Mar 2021 01:19:46

FDA-CBER-2022-1614-2894783

US3642086
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:19:14
DataPoint Verified.		23 Mar 2021 17:50:46
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered '03 Mar 2021'	Jennifer Morales (b) (4) (b) (4)	04 Mar 2021 01:19:46

FDA-CBER-2022-1614-2894784

US3642086
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:19:14
DataPoint Verified.		23 Mar 2021 17:50:46
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered 'Contact Made (CONTACT MADE)'	Jennifer Morales (b) (4) (b) (4)	04 Mar 2021 01:19:46

US3642086
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:19:14
DataPoint Verified.		23 Mar 2021 17:50:46
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered empty.	Jennifer Morales (b) (4) (b) (4)	04 Mar 2021 01:19:46

FDA-CBER-2022-1614-2894786

US3642086
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:14:49
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:19:14
DataPoint Verified.		23 Mar 2021 17:50:50
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered 'Yes (Y)'	Jennifer Morales (b) (4) (b) (4)	04 Mar 2021 01:19:52

FDA-CBER-2022-1614-2894787

US3642086
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:14:49
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:19:14
User entered '1'	System	04 Mar 2021 01:19:52

FDA-CBER-2022-1614-2894788

US3642086
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:40
DataPoint Verified.		20 Apr 2021 17:01:23
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:28:27
User entered 'Yes (Y)'	Son Do (b) (4)	30 Mar 2021 15:12:37

US3642086
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:40
DataPoint Verified.		20 Apr 2021 17:01:23
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:28:27
User entered '25 Mar 2021'	Son Do (b) (4)	30 Mar 2021 15:12:37

US3642086
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
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 11:55:40
DataPoint Verified.		20 Apr 2021 17:01:23
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:28:27
User entered 'Clinic (Clinic)'	Son Do (b) (4)	30 Mar 2021 15:12:37

US3642086
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:40
User entered 'VISIT4'	System	30 Mar 2021 15:12:37

FDA-CBER-2022-1614-2894792

US3642086
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:40
DataPoint Verified.		20 Apr 2021 17:01:26
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:28:27
User entered 'No (N)'	Son Do (b) (4)	30 Mar 2021 15:12:44

US3642086
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:40
DataPoint Verified.		20 Apr 2021 17:01:26
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:28:27
User entered empty.	Son Do (b) (4)	30 Mar 2021 15:12:44

FDA-CBER-2022-1614-2894794

US3642086
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:40
DataPoint Verified.		20 Apr 2021 17:01:26
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:28:27
User entered empty.	Son Do (b) (4)	30 Mar 2021 15:12:44

FDA-CBER-2022-1614-2894795

US3642086
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:40
User entered empty.	System	30 Mar 2021 15:12:44

FDA-CBER-2022-1614-2894796

US3642086
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:40
DataPoint Verified.		20 Apr 2021 17:01:26
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:28:27
User entered empty.	Son Do (b) (4)	30 Mar 2021 15:12:44

FDA-CBER-2022-1614-2894797

US3642086
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:40
DataPoint Verified.		20 Apr 2021 17:01:26
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:28:27
User entered empty.	Son Do (b) (4)	30 Mar 2021 15:12:44

FDA-CBER-2022-1614-2894798

US3642086
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:40
DataPoint Verified.		20 Apr 2021 17:01:26
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:28:27
User entered empty.	Son Do (b) (4)	30 Mar 2021 15:12:44

FDA-CBER-2022-1614-2894799

US3642086
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:40
DataPoint Verified.		20 Apr 2021 17:01:26
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:28:27
User entered empty.	Son Do (b) (4)	30 Mar 2021 15:12:44

FDA-CBER-2022-1614-2894800

US3642086
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:40
User entered empty.	System	30 Mar 2021 15:12:44

US3642086
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:40
DataPoint Verified.		20 Apr 2021 17:01:26
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:28:27
User entered empty.	Son Do (b) (4)	30 Mar 2021 15:12:44

US3642086
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:40
User entered empty.	System	30 Mar 2021 15:12:44

FDA-CBER-2022-1614-2894803

US3642086
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:40
DataPoint Verified.		20 Apr 2021 17:01:26
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:28:27
User entered empty.	Son Do (b) (4)	30 Mar 2021 15:12:44

US3642086
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:40
User entered empty.	System	30 Mar 2021 15:12:44

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US3642086
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:40
DataPoint Verified.		20 Apr 2021 17:01:26
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:28:27
User entered empty.	Son Do (b) (4)	30 Mar 2021 15:12:44

US3642086
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:40
User entered empty.	System	30 Mar 2021 15:12:44

FDA-CBER-2022-1614-2894807

US3642086
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:40

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US3642086
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:40

FDA-CBER-2022-1614-2894809

US3642086
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:14:49
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:40
DataPoint Verified.		20 Apr 2021 17:01:31
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:28:27
User entered 'No (N)'	Son Do (b) (4)	30 Mar 2021 15:12:49

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US3642086
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:14:49
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:40
DataPoint Verified.		20 Apr 2021 17:01:31
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:28:27
User entered empty.	Son Do (b) (4)	30 Mar 2021 15:12:49

US3642086
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:14:49
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:40
DataPoint Verified.		20 Apr 2021 17:01:39
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:28:27
User entered 'Yes (Y)'	Son Do (b) (4)	30 Mar 2021 15:13:00

US3642086
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:14:49
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:40
DataPoint Verified.		20 Apr 2021 17:01:39
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:28:27
User entered '25 Mar 2021'	Son Do (b) (4)	30 Mar 2021 15:13:00

US3642086
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:14:49
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:40
DataPoint Verified.		20 Apr 2021 17:01:39
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:28:27
User entered '15:21'	Son Do (b) (4)	30 Mar 2021 15:13:00

US3642086
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:14:49
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:40
User entered '25 Mar 2021 15:21'	System	30 Mar 2021 15:13:00

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US3642086
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:14:49
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:40
DataPoint Verified.		20 Apr 2021 17:01:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:28:27
User entered 'Yes (Y)'	Son Do (b) (4)	30 Mar 2021 15:13:05

US3642086
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:14:49
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:40
User entered '1'	System	30 Mar 2021 15:13:05

US3642086
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Was Contact Attempted?

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	28 Apr 2021 23:40:00
User entered 'Yes (Y)'	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:35:20

FDA-CBER-2022-1614-2894818

US3642086
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	28 Apr 2021 23:40:00
User entered '28 Apr 2021'	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:35:20

FDA-CBER-2022-1614-2894819

US3642086
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Please select one status for the follow-up contact

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	28 Apr 2021 23:40:00
User entered 'Contact Made (CONTACT MADE)'	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:35:20

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US3642086
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	28 Apr 2021 23:40:00
User entered empty.	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:35:20

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US3642086
Folder: Safety Call Day 239 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:14:49
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	28 Apr 2021 23:40:00
User entered 'Yes (Y)'	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:35:27

FDA-CBER-2022-1614-2894822

US3642086
Folder: Safety Call Day 239 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:14:49
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	28 Apr 2021 22:35:27

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: COVID-19 Contact
Generated On: 10 Jun 2021 09:14:49
Date of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:31
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:18:57
User entered '22 Dec 2020'	Colleen McLellan (b) (4) (b) (4)	22 Dec 2020 19:32:38

FDA-CBER-2022-1614-2894824

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: COVID-19 Contact
Generated On: 10 Jun 2021 09:14:49
Time of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:31
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:18:57
User entered '10:30'	Colleen McLellan (b) (4) (b) (4)	22 Dec 2020 19:32:38

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: COVID-19 Contact
Generated On: 10 Jun 2021 09:14:49
Date and Time of Contact (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:31
User entered '22 Dec 2020 10:30'	System	22 Dec 2020 19:32:38

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: COVID-19 Contact
Generated On: 10 Jun 2021 09:14:49
Type of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:31
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:18:57
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Colleen McLellan (b) (4)	22 Dec 2020 19:32:38

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: COVID-19 Contact
Generated On: 10 Jun 2021 09:14:49
Has the subject reported symptoms of SARS-COV-2?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:31
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:18:57
User entered 'Yes (Y)'	Colleen McLellan (b) (4) (b) (4)	22 Dec 2020 19:32:38

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:14:49
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Day 1 (Day 1)'	Nancy Tang (b) (4)	23 Dec 2020 20:15:26

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:14:49
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '18 Dec 2020'	Nancy Tang (b) (4)	23 Dec 2020 20:15:26

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:14:49
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '0'	Nancy Tang (b) (4)	23 Dec 2020 20:15:26

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered missing code ND - Not Done.	Nancy Tang (b) (4)	23 Dec 2020 20:15:26

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User entered '%'	System	23 Dec 2020 20:15:26

FDA-CBER-2022-1614-2894833

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:14:49
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered missing code ND - Not Done.	Nancy Tang (b) (4)	23 Dec 2020 20:15:26

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:14:49
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	23 Dec 2020 20:15:26

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:14:49
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:15:26

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:14:49
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:15:26

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:14:49
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:15:26

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:14:49
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:15:26

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:14:49
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:15:26

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:14:49
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	23 Dec 2020 20:15:26

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:14:49
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	23 Dec 2020 20:15:26

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:14:49
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:15:26

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:14:49
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:15:26

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:14:49
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:15:26

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:14:49
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:15:26

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:14:49
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:15:26

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:14:49
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:15:26

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:14:49
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	23 Dec 2020 20:15:26

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:14:49
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:15:26

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:14:49
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Day 2 (Day 2)'	Nancy Tang (b) (4)	23 Dec 2020 20:16:53

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:14:49
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '19 Dec 2020'	Nancy Tang (b) (4)	23 Dec 2020 20:16:53

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:14:49
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '0'	Nancy Tang (b) (4)	23 Dec 2020 20:16:53

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered missing code ND - Not Done.	Nancy Tang (b) (4)	23 Dec 2020 20:16:53

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User entered '%'	System	23 Dec 2020 20:16:53

FDA-CBER-2022-1614-2894855

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:14:49
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '99.1' F	Nancy Tang (b) (4)	23 Dec 2020 20:16:53

FDA-CBER-2022-1614-2894856

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:14:49
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	23 Dec 2020 20:16:53

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:14:49
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:16:53

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:14:49
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:16:53

FDA-CBER-2022-1614-2894859

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:14:49
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:16:53

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:14:49
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	23 Dec 2020 20:16:53

FDA-CBER-2022-1614-2894861

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:14:49
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Severe (Severe)'	Nancy Tang (b) (4)	23 Dec 2020 20:16:53

FDA-CBER-2022-1614-2894862

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:14:49
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Severe (Severe)'	Nancy Tang (b) (4)	23 Dec 2020 20:16:53

FDA-CBER-2022-1614-2894863

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:14:49
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	23 Dec 2020 20:16:53

FDA-CBER-2022-1614-2894864

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:14:49
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:16:53

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:14:49
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:16:53

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:14:49
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:16:53

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:14:49
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:16:53

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:14:49
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:16:53

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:14:49
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:16:53

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:14:49
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:16:53

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:14:49
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:16:53

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:14:49
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Day 3 (Day 3)'	Nancy Tang (b) (4)	23 Dec 2020 20:18:32

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:14:49
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '20 Dec 2020'	Nancy Tang (b) (4)	23 Dec 2020 20:18:32

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:14:49
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '0'	Nancy Tang (b) (4)	23 Dec 2020 20:18:32

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered missing code ND - Not Done.	Nancy Tang (b) (4)	23 Dec 2020 20:18:32

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User entered '%'	System	23 Dec 2020 20:18:32

FDA-CBER-2022-1614-2894877

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:14:49
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '97' F	Nancy Tang (b) (4)	23 Dec 2020 20:18:32

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:14:49
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:18:32

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:14:49
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:18:32

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:14:49
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:18:32

FDA-CBER-2022-1614-2894881

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:14:49
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:18:32

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:14:49
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Moderate (Moderate)'	Nancy Tang (b) (4)	23 Dec 2020 20:18:32

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:14:49
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:18:32

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:14:49
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Severe (Severe)'	Nancy Tang (b) (4)	23 Dec 2020 20:18:32

FDA-CBER-2022-1614-2894885

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:14:49
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:18:32

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:14:49
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:18:32

FDA-CBER-2022-1614-2894887

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:14:49
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:18:32

FDA-CBER-2022-1614-2894888

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:14:49
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:18:32

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:14:49
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:18:32

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:14:49
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:18:32

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:14:49
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:18:32

FDA-CBER-2022-1614-2894892

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:14:49
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:18:32

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:14:49
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:18:32

FDA-CBER-2022-1614-2894894

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:14:49
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Day 4 (Day 4)'	Nancy Tang (b) (4)	23 Dec 2020 20:22:18

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:14:49
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '21 Dec 2020'	Nancy Tang (b) (4)	23 Dec 2020 20:22:18

FDA-CBER-2022-1614-2894896

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:14:49
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '0'	Nancy Tang (b) (4)	23 Dec 2020 20:22:18

FDA-CBER-2022-1614-2894897

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered missing code ND - Not Done.	Nancy Tang (b) (4)	23 Dec 2020 20:22:18

FDA-CBER-2022-1614-2894898

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User entered '%'	System	23 Dec 2020 20:22:18

FDA-CBER-2022-1614-2894899

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:14:49
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '98' F	Nancy Tang (b) (4)	23 Dec 2020 20:22:18

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:14:49
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:22:18

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:14:49
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:22:18

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:14:49
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:22:18

FDA-CBER-2022-1614-2894903

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:14:49
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:22:18

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:14:49
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Moderate (Moderate)'	Nancy Tang (b) (4)	23 Dec 2020 20:22:18

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:14:49
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:22:18

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:14:49
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Severe (Severe)'	Nancy Tang (b) (4)	23 Dec 2020 20:22:18

FDA-CBER-2022-1614-2894907

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:14:49
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:22:18

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:14:49
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:22:18

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:14:49
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:22:18

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:14:49
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:22:18

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:14:49
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:22:18

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:14:49
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:22:18

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:14:49
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:22:18

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:14:49
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:22:18

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:14:49
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:22:18

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:14:49
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Day 5 (Day 5)'	Nancy Tang (b) (4)	23 Dec 2020 20:24:38

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:14:49
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '22 Dec 2020'	Nancy Tang (b) (4)	23 Dec 2020 20:24:38

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:14:49
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '0'	Nancy Tang (b) (4)	23 Dec 2020 20:24:38

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '98'	Nancy Tang (b) (4)	23 Dec 2020 20:24:38

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User entered '%'	System	23 Dec 2020 20:24:38

FDA-CBER-2022-1614-2894921

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:14:49
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '98.5' F	Nancy Tang (b) (4)	23 Dec 2020 20:24:38

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:14:49
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:24:38

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:14:49
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	23 Dec 2020 20:24:38

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:14:49
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:24:38

FDA-CBER-2022-1614-2894925

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:14:49
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:24:38

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:14:49
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Moderate (Moderate)'	Nancy Tang (b) (4)	23 Dec 2020 20:24:38

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:14:49
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:24:38

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:14:49
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Moderate (Moderate)'	Nancy Tang (b) (4)	23 Dec 2020 20:24:38

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:14:49
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:24:38

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:14:49
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:24:38

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:14:49
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:24:38

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:14:49
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:24:38

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:14:49
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:24:38

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:14:49
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:24:38

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:14:49
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:24:38

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:14:49
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:24:38

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:14:49
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:24:38

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:14:49
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Day 6 (Day 6)'	Nancy Tang (b) (4)	23 Dec 2020 20:26:14

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:14:49
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '23 Dec 2020'	Nancy Tang (b) (4)	23 Dec 2020 20:26:14

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:14:49
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '0'	Nancy Tang (b) (4)	23 Dec 2020 20:26:14

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '99'	Nancy Tang (b) (4)	23 Dec 2020 20:26:14

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User entered '%'	System	23 Dec 2020 20:26:14

FDA-CBER-2022-1614-2894943

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:14:49
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '99.9' F	Nancy Tang (b) (4)	23 Dec 2020 20:26:14

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:14:49
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	23 Dec 2020 20:26:14

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:14:49
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	23 Dec 2020 20:26:14

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:14:49
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:26:14

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:14:49
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:26:14

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:14:49
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Moderate (Moderate)'	Nancy Tang (b) (4)	23 Dec 2020 20:26:14

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:14:49
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Moderate (Moderate)'	Nancy Tang (b) (4)	23 Dec 2020 20:26:14

FDA-CBER-2022-1614-2894950

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:14:49
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Moderate (Moderate)'	Nancy Tang (b) (4)	23 Dec 2020 20:26:14

FDA-CBER-2022-1614-2894951

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:14:49
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	23 Dec 2020 20:26:14

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:14:49
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:26:14

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:14:49
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:26:14

FDA-CBER-2022-1614-2894954

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:14:49
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:26:14

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:14:49
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:26:14

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:14:49
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	23 Dec 2020 20:26:14

FDA-CBER-2022-1614-2894957

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:14:49
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	23 Dec 2020 20:26:14

FDA-CBER-2022-1614-2894958

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:14:49
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:26:14

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:14:49
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	23 Dec 2020 20:26:14

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:14:49
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Day 7 (Day 7)'	Nancy Tang (b) (4)	24 Dec 2020 22:26:41

FDA-CBER-2022-1614-2894961

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:14:49
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '24 Dec 2020'	Nancy Tang (b) (4)	24 Dec 2020 22:26:41

FDA-CBER-2022-1614-2894962

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:14:49
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '0'	Nancy Tang (b) (4)	24 Dec 2020 22:26:41

FDA-CBER-2022-1614-2894963

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '98'	Nancy Tang (b) (4)	24 Dec 2020 22:26:41

FDA-CBER-2022-1614-2894964

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User entered '%'	System	24 Dec 2020 22:26:41

FDA-CBER-2022-1614-2894965

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:14:49
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '100' F	Nancy Tang (b) (4)	24 Dec 2020 22:26:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:14:49
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	24 Dec 2020 22:26:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:14:49
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	24 Dec 2020 22:26:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:14:49
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	24 Dec 2020 22:26:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:14:49
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	24 Dec 2020 22:26:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:14:49
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Moderate (Moderate)'	Nancy Tang (b) (4)	24 Dec 2020 22:26:41

FDA-CBER-2022-1614-2894971

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:14:49
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Moderate (Moderate)'	Nancy Tang (b) (4)	24 Dec 2020 22:26:41

FDA-CBER-2022-1614-2894972

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:14:49
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Moderate (Moderate)'	Nancy Tang (b) (4)	24 Dec 2020 22:26:41

FDA-CBER-2022-1614-2894973

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:14:49
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	24 Dec 2020 22:26:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:14:49
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	24 Dec 2020 22:26:41

FDA-CBER-2022-1614-2894975

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:14:49
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	24 Dec 2020 22:26:41

FDA-CBER-2022-1614-2894976

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:14:49
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	24 Dec 2020 22:26:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:14:49
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	24 Dec 2020 22:26:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:14:49
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	24 Dec 2020 22:26:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:14:49
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	24 Dec 2020 22:26:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:14:49
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	24 Dec 2020 22:26:41

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:14:49
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	24 Dec 2020 22:26:41

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:14:49
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Day 8 (Day 8)'	Nancy Tang (b) (4)	25 Dec 2020 19:33:40

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:14:49
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '25 Dec 2020'	Nancy Tang (b) (4)	25 Dec 2020 19:33:40

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:14:49
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '0'	Nancy Tang (b) (4)	25 Dec 2020 19:33:40

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '98'	Nancy Tang (b) (4)	25 Dec 2020 19:33:40

FDA-CBER-2022-1614-2894986

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User entered '%'	System	25 Dec 2020 19:33:40

FDA-CBER-2022-1614-2894987

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:14:49
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '100.8' F	Nancy Tang (b) (4)	25 Dec 2020 19:33:40

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:14:49
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	25 Dec 2020 19:33:40

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:14:49
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	25 Dec 2020 19:33:40

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:14:49
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	25 Dec 2020 19:33:40

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:14:49
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	25 Dec 2020 19:33:40

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:14:49
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Moderate (Moderate)'	Nancy Tang (b) (4)	25 Dec 2020 19:33:40

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:14:49
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Moderate (Moderate)'	Nancy Tang (b) (4)	25 Dec 2020 19:33:40

FDA-CBER-2022-1614-2894994

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:14:49
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Moderate (Moderate)'	Nancy Tang (b) (4)	25 Dec 2020 19:33:40

FDA-CBER-2022-1614-2894995

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:14:49
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	25 Dec 2020 19:33:40

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:14:49
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	25 Dec 2020 19:33:40

FDA-CBER-2022-1614-2894997

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:14:49
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	25 Dec 2020 19:33:40

FDA-CBER-2022-1614-2894998

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:14:49
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	25 Dec 2020 19:33:40

FDA-CBER-2022-1614-2894999

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:14:49
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	25 Dec 2020 19:33:40

FDA-CBER-2022-1614-2895000

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:14:49
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	25 Dec 2020 19:33:40

FDA-CBER-2022-1614-2895001

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:14:49
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	25 Dec 2020 19:33:40

FDA-CBER-2022-1614-2895002

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:14:49
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	25 Dec 2020 19:33:40

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:14:49
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	25 Dec 2020 19:33:40

FDA-CBER-2022-1614-2895004

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:14:49
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Day 9 (Day 9)'	Nancy Tang (b) (4)	26 Dec 2020 22:50:06

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:14:49
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '26 Dec 2020'	Nancy Tang (b) (4)	26 Dec 2020 22:50:06

FDA-CBER-2022-1614-2895006

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:14:49
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '0'	Nancy Tang (b) (4)	26 Dec 2020 22:50:06

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '98'	Nancy Tang (b) (4)	26 Dec 2020 22:50:06

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User entered '%'	System	26 Dec 2020 22:50:06

FDA-CBER-2022-1614-2895009

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:14:49
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '100.7' F	Nancy Tang (b) (4)	26 Dec 2020 22:50:06

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:14:49
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	26 Dec 2020 22:50:06

FDA-CBER-2022-1614-2895011

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:14:49
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	26 Dec 2020 22:50:06

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:14:49
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	26 Dec 2020 22:50:06

FDA-CBER-2022-1614-2895013

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:14:49
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	26 Dec 2020 22:50:06

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:14:49
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Moderate (Moderate)'	Nancy Tang (b) (4)	26 Dec 2020 22:50:06

FDA-CBER-2022-1614-2895015

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:14:49
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Moderate (Moderate)'	Nancy Tang (b) (4)	26 Dec 2020 22:50:06

FDA-CBER-2022-1614-2895016

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:14:49
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Moderate (Moderate)'	Nancy Tang (b) (4)	26 Dec 2020 22:50:06

FDA-CBER-2022-1614-2895017

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:14:49
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	26 Dec 2020 22:50:06

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:14:49
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	26 Dec 2020 22:50:06

FDA-CBER-2022-1614-2895019

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:14:49
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	26 Dec 2020 22:50:06

FDA-CBER-2022-1614-2895020

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:14:49
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	26 Dec 2020 22:50:06

FDA-CBER-2022-1614-2895021

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:14:49
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	26 Dec 2020 22:50:06

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:14:49
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	26 Dec 2020 22:50:06

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:14:49
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	26 Dec 2020 22:50:06

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:14:49
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	26 Dec 2020 22:50:06

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:14:49
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	26 Dec 2020 22:50:06

FDA-CBER-2022-1614-2895026

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:14:49
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Day 10 (Day 10)'	Nancy Tang (b) (4)	27 Dec 2020 21:09:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:14:49
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '27 Dec 2020'	Nancy Tang (b) (4)	27 Dec 2020 21:09:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:14:49
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '0'	Nancy Tang (b) (4)	27 Dec 2020 21:09:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '98'	Nancy Tang (b) (4)	27 Dec 2020 21:09:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User entered '%'	System	27 Dec 2020 21:09:41

FDA-CBER-2022-1614-2895031

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:14:49
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '100' F	Nancy Tang (b) (4)	27 Dec 2020 21:09:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:14:49
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	27 Dec 2020 21:09:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:14:49
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	27 Dec 2020 21:09:41

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:14:49
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	27 Dec 2020 21:09:41

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:14:49
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	27 Dec 2020 21:09:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:14:49
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Moderate (Moderate)'	Nancy Tang (b) (4)	27 Dec 2020 21:09:41

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:14:49
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	27 Dec 2020 21:09:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:14:49
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Moderate (Moderate)'	Nancy Tang (b) (4)	27 Dec 2020 21:09:41

FDA-CBER-2022-1614-2895039

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:14:49
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	27 Dec 2020 21:09:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:14:49
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	27 Dec 2020 21:09:41

FDA-CBER-2022-1614-2895041

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:14:49
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	27 Dec 2020 21:09:41

FDA-CBER-2022-1614-2895042

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:14:49
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	27 Dec 2020 21:09:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:14:49
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	27 Dec 2020 21:09:41

FDA-CBER-2022-1614-2895044

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:14:49
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	27 Dec 2020 21:09:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:14:49
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	27 Dec 2020 21:09:41

FDA-CBER-2022-1614-2895046

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:14:49
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	27 Dec 2020 21:09:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:14:49
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	27 Dec 2020 21:09:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:14:49
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Day 11 (Day 11)'	Nancy Tang (b) (4)	29 Dec 2020 01:57:35

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:14:49
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '28 Dec 2020'	Nancy Tang (b) (4)	29 Dec 2020 01:57:35

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:14:49
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '0'	Nancy Tang (b) (4)	29 Dec 2020 01:57:35

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '97'	Nancy Tang (b) (4)	29 Dec 2020 01:57:35

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User entered '%'	System	29 Dec 2020 01:57:35

FDA-CBER-2022-1614-2895053

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:14:49
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '100.7' F	Nancy Tang (b) (4)	29 Dec 2020 01:57:35

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:14:49
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	29 Dec 2020 01:57:35

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:14:49
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Moderate (Moderate)'	Nancy Tang (b) (4)	29 Dec 2020 01:57:35

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:14:49
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	29 Dec 2020 01:57:35

FDA-CBER-2022-1614-2895057

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:14:49
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	29 Dec 2020 01:57:35

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:14:49
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	29 Dec 2020 01:57:35

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:14:49
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	29 Dec 2020 01:57:35

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:14:49
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Moderate (Moderate)'	Nancy Tang (b) (4)	29 Dec 2020 01:57:35

FDA-CBER-2022-1614-2895061

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:14:49
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	29 Dec 2020 01:57:35

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:14:49
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	29 Dec 2020 01:57:35

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:14:49
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	29 Dec 2020 01:57:35

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:14:49
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	29 Dec 2020 01:57:35

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:14:49
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	29 Dec 2020 01:57:35

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:14:49
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	29 Dec 2020 01:57:35

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:14:49
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	29 Dec 2020 01:57:35

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:14:49
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	29 Dec 2020 01:57:35

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:14:49
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	29 Dec 2020 01:57:35

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (12)
Generated On: 10 Jun 2021 09:14:49
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Day 12 (Day 12)'	Nancy Tang (b) (4)	29 Dec 2020 20:47:59

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (12)
Generated On: 10 Jun 2021 09:14:49
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '29 Dec 2020'	Nancy Tang (b) (4)	29 Dec 2020 20:47:59

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (12)
Generated On: 10 Jun 2021 09:14:49
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '0'	Nancy Tang (b) (4)	29 Dec 2020 20:47:59

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (12)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '99'	Nancy Tang (b) (4)	29 Dec 2020 20:47:59

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (12)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User entered '%'	System	29 Dec 2020 20:47:59

FDA-CBER-2022-1614-2895075

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (12)
Generated On: 10 Jun 2021 09:14:49
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '100.2' F	Nancy Tang (b) (4)	29 Dec 2020 20:47:59

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (12)
Generated On: 10 Jun 2021 09:14:49
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	29 Dec 2020 20:47:59

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (12)
Generated On: 10 Jun 2021 09:14:49
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Moderate (Moderate)'	Nancy Tang (b) (4)	29 Dec 2020 20:47:59

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (12)
Generated On: 10 Jun 2021 09:14:49
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	29 Dec 2020 20:47:59

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (12)
Generated On: 10 Jun 2021 09:14:49
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	29 Dec 2020 20:47:59

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (12)
Generated On: 10 Jun 2021 09:14:49
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	29 Dec 2020 20:47:59

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (12)
Generated On: 10 Jun 2021 09:14:49
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	29 Dec 2020 20:47:59

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (12)
Generated On: 10 Jun 2021 09:14:49
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	29 Dec 2020 20:47:59

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (12)
Generated On: 10 Jun 2021 09:14:49
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Moderate (Moderate)'	Nancy Tang (b) (4)	29 Dec 2020 20:47:59

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (12)
Generated On: 10 Jun 2021 09:14:49
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	29 Dec 2020 20:47:59

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (12)
Generated On: 10 Jun 2021 09:14:49
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	29 Dec 2020 20:47:59

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (12)
Generated On: 10 Jun 2021 09:14:49
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	29 Dec 2020 20:47:59

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (12)
Generated On: 10 Jun 2021 09:14:49
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	29 Dec 2020 20:47:59

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (12)
Generated On: 10 Jun 2021 09:14:49
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	29 Dec 2020 20:47:59

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (12)
Generated On: 10 Jun 2021 09:14:49
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	29 Dec 2020 20:47:59

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (12)
Generated On: 10 Jun 2021 09:14:49
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	29 Dec 2020 20:47:59

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (12)
Generated On: 10 Jun 2021 09:14:49
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	29 Dec 2020 20:47:59

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (13)
Generated On: 10 Jun 2021 09:14:49
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Day 13 (Day 13)'	Nancy Tang (b) (4)	30 Dec 2020 21:47:05

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (13)
Generated On: 10 Jun 2021 09:14:49
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '30 Dec 2020'	Nancy Tang (b) (4)	30 Dec 2020 21:47:05

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (13)
Generated On: 10 Jun 2021 09:14:49
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '0'	Nancy Tang (b) (4)	30 Dec 2020 21:47:05

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (13)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '99' reason for change: Data Entry Error	Nancy Tang (b) (4)	30 Dec 2020 21:48:27
User entered '99%' (non-conformant).	Nancy Tang (b) (4)	30 Dec 2020 21:47:05

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (13)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User entered '%'	System	30 Dec 2020 21:48:27
User entered empty.	System	30 Dec 2020 21:47:05

FDA-CBER-2022-1614-2895097

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (13)
Generated On: 10 Jun 2021 09:14:49
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '98' F	Nancy Tang (b) (4)	30 Dec 2020 21:47:05

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (13)
Generated On: 10 Jun 2021 09:14:49
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	30 Dec 2020 21:47:05

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (13)
Generated On: 10 Jun 2021 09:14:49
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Severe (Severe)'	Nancy Tang (b) (4)	30 Dec 2020 21:47:05

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (13)
Generated On: 10 Jun 2021 09:14:49
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	30 Dec 2020 21:47:05

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (13)
Generated On: 10 Jun 2021 09:14:49
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	30 Dec 2020 21:47:05

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (13)
Generated On: 10 Jun 2021 09:14:49
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	30 Dec 2020 21:47:05

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (13)
Generated On: 10 Jun 2021 09:14:49
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	30 Dec 2020 21:47:05

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (13)
Generated On: 10 Jun 2021 09:14:49
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	30 Dec 2020 21:47:05

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (13)
Generated On: 10 Jun 2021 09:14:49
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	30 Dec 2020 21:47:05

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (13)
Generated On: 10 Jun 2021 09:14:49
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	30 Dec 2020 21:47:05

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (13)
Generated On: 10 Jun 2021 09:14:49
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	30 Dec 2020 21:47:05

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (13)
Generated On: 10 Jun 2021 09:14:49
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	30 Dec 2020 21:47:05

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (13)
Generated On: 10 Jun 2021 09:14:49
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	30 Dec 2020 21:47:05

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (13)
Generated On: 10 Jun 2021 09:14:49
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	30 Dec 2020 21:47:05

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (13)
Generated On: 10 Jun 2021 09:14:49
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	30 Dec 2020 21:47:05

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (13)
Generated On: 10 Jun 2021 09:14:49
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	30 Dec 2020 21:47:05

FDA-CBER-2022-1614-2895113

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (13)
Generated On: 10 Jun 2021 09:14:49
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	30 Dec 2020 21:47:05

FDA-CBER-2022-1614-2895114

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (14)
Generated On: 10 Jun 2021 09:14:49
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Day 14 (Day 14)'	Nancy Tang (b) (4)	31 Dec 2020 20:42:35

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (14)
Generated On: 10 Jun 2021 09:14:49
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '31 Dec 2020'	Nancy Tang (b) (4)	31 Dec 2020 20:42:35

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (14)
Generated On: 10 Jun 2021 09:14:49
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '0'	Nancy Tang (b) (4)	31 Dec 2020 20:42:35

FDA-CBER-2022-1614-2895117

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (14)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '99'	Nancy Tang (b) (4)	31 Dec 2020 20:42:35

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (14)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User entered '%'	System	31 Dec 2020 20:42:35

FDA-CBER-2022-1614-2895119

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (14)
Generated On: 10 Jun 2021 09:14:49
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '98.8' F	Nancy Tang (b) (4)	31 Dec 2020 20:42:35

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (14)
Generated On: 10 Jun 2021 09:14:49
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	31 Dec 2020 20:42:35

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (14)
Generated On: 10 Jun 2021 09:14:49
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Moderate (Moderate)'	Nancy Tang (b) (4)	31 Dec 2020 20:42:35

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (14)
Generated On: 10 Jun 2021 09:14:49
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	31 Dec 2020 20:42:35

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (14)
Generated On: 10 Jun 2021 09:14:49
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	31 Dec 2020 20:42:35

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (14)
Generated On: 10 Jun 2021 09:14:49
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	31 Dec 2020 20:42:35

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (14)
Generated On: 10 Jun 2021 09:14:49
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	31 Dec 2020 20:42:35

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (14)
Generated On: 10 Jun 2021 09:14:49
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	31 Dec 2020 20:42:35

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (14)
Generated On: 10 Jun 2021 09:14:49
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	31 Dec 2020 20:42:35

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (14)
Generated On: 10 Jun 2021 09:14:49
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	31 Dec 2020 20:42:35

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (14)
Generated On: 10 Jun 2021 09:14:49
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	31 Dec 2020 20:42:35

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (14)
Generated On: 10 Jun 2021 09:14:49
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	31 Dec 2020 20:42:35

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (14)
Generated On: 10 Jun 2021 09:14:49
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	31 Dec 2020 20:42:35

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (14)
Generated On: 10 Jun 2021 09:14:49
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	31 Dec 2020 20:42:35

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (14)
Generated On: 10 Jun 2021 09:14:49
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	31 Dec 2020 20:42:35

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (14)
Generated On: 10 Jun 2021 09:14:49
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	31 Dec 2020 20:42:35

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (14)
Generated On: 10 Jun 2021 09:14:49
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	31 Dec 2020 20:42:35

FDA-CBER-2022-1614-2895136

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (15)
Generated On: 10 Jun 2021 09:14:49
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Day 15 (Day 15)'	Nancy Tang (b) (4)	02 Jan 2021 13:23:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (15)
Generated On: 10 Jun 2021 09:14:49
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '01 Jan 2021'	Nancy Tang (b) (4)	02 Jan 2021 13:23:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (15)
Generated On: 10 Jun 2021 09:14:49
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '0'	Nancy Tang (b) (4)	02 Jan 2021 13:23:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (15)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '99'	Nancy Tang (b) (4)	02 Jan 2021 13:23:41

FDA-CBER-2022-1614-2895140

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (15)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User entered '%'	System	02 Jan 2021 13:23:41

FDA-CBER-2022-1614-2895141

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (15)
Generated On: 10 Jun 2021 09:14:49
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '98.8' F	Nancy Tang (b) (4)	02 Jan 2021 13:23:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (15)
Generated On: 10 Jun 2021 09:14:49
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	02 Jan 2021 13:23:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (15)
Generated On: 10 Jun 2021 09:14:49
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Moderate (Moderate)'	Nancy Tang (b) (4)	02 Jan 2021 13:23:41

FDA-CBER-2022-1614-2895144

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (15)
Generated On: 10 Jun 2021 09:14:49
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	02 Jan 2021 13:23:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (15)
Generated On: 10 Jun 2021 09:14:49
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	02 Jan 2021 13:23:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (15)
Generated On: 10 Jun 2021 09:14:49
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	02 Jan 2021 13:23:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (15)
Generated On: 10 Jun 2021 09:14:49
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	02 Jan 2021 13:23:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (15)
Generated On: 10 Jun 2021 09:14:49
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	02 Jan 2021 13:23:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (15)
Generated On: 10 Jun 2021 09:14:49
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Moderate (Moderate)'	Nancy Tang (b) (4)	02 Jan 2021 13:23:41

FDA-CBER-2022-1614-2895150

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (15)
Generated On: 10 Jun 2021 09:14:49
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	02 Jan 2021 13:23:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (15)
Generated On: 10 Jun 2021 09:14:49
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	02 Jan 2021 13:23:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (15)
Generated On: 10 Jun 2021 09:14:49
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	02 Jan 2021 13:23:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (15)
Generated On: 10 Jun 2021 09:14:49
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	02 Jan 2021 13:23:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (15)
Generated On: 10 Jun 2021 09:14:49
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	02 Jan 2021 13:23:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (15)
Generated On: 10 Jun 2021 09:14:49
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	02 Jan 2021 13:23:41

FDA-CBER-2022-1614-2895156

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (15)
Generated On: 10 Jun 2021 09:14:49
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	02 Jan 2021 13:23:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (15)
Generated On: 10 Jun 2021 09:14:49
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	02 Jan 2021 13:23:41

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (16)
Generated On: 10 Jun 2021 09:14:49
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Day 16 (Day 16)'	Nancy Tang (b) (4)	03 Jan 2021 17:15:59

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (16)
Generated On: 10 Jun 2021 09:14:49
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '02 Jan 2021'	Nancy Tang (b) (4)	03 Jan 2021 17:15:59

FDA-CBER-2022-1614-2895160

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (16)
Generated On: 10 Jun 2021 09:14:49
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '0'	Nancy Tang (b) (4)	03 Jan 2021 17:15:59

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (16)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '99'	Nancy Tang (b) (4)	03 Jan 2021 17:15:59

FDA-CBER-2022-1614-2895162

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (16)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User entered '%'	System	03 Jan 2021 17:15:59

FDA-CBER-2022-1614-2895163

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (16)
Generated On: 10 Jun 2021 09:14:49
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '98' F	Nancy Tang (b) (4)	03 Jan 2021 17:15:59

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (16)
Generated On: 10 Jun 2021 09:14:49
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	03 Jan 2021 17:15:59

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (16)
Generated On: 10 Jun 2021 09:14:49
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	03 Jan 2021 17:15:59

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (16)
Generated On: 10 Jun 2021 09:14:49
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	03 Jan 2021 17:15:59

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (16)
Generated On: 10 Jun 2021 09:14:49
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	03 Jan 2021 17:15:59

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (16)
Generated On: 10 Jun 2021 09:14:49
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	03 Jan 2021 17:15:59

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (16)
Generated On: 10 Jun 2021 09:14:49
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	03 Jan 2021 17:15:59

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (16)
Generated On: 10 Jun 2021 09:14:49
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	03 Jan 2021 17:15:59

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (16)
Generated On: 10 Jun 2021 09:14:49
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	03 Jan 2021 17:15:59

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (16)
Generated On: 10 Jun 2021 09:14:49
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	03 Jan 2021 17:15:59

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (16)
Generated On: 10 Jun 2021 09:14:49
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	03 Jan 2021 17:15:59

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (16)
Generated On: 10 Jun 2021 09:14:49
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	03 Jan 2021 17:15:59

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (16)
Generated On: 10 Jun 2021 09:14:49
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	03 Jan 2021 17:15:59

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (16)
Generated On: 10 Jun 2021 09:14:49
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	03 Jan 2021 17:15:59

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (16)
Generated On: 10 Jun 2021 09:14:49
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	03 Jan 2021 17:15:59

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (16)
Generated On: 10 Jun 2021 09:14:49
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	03 Jan 2021 17:15:59

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (16)
Generated On: 10 Jun 2021 09:14:49
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	03 Jan 2021 17:15:59

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (17)
Generated On: 10 Jun 2021 09:14:49
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Day 17 (Day 17)'	Nancy Tang (b) (4)	04 Jan 2021 03:05:26

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (17)
Generated On: 10 Jun 2021 09:14:49
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '03 Jan 2021'	Nancy Tang (b) (4)	04 Jan 2021 03:05:26

FDA-CBER-2022-1614-2895182

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (17)
Generated On: 10 Jun 2021 09:14:49
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '0'	Nancy Tang (b) (4)	04 Jan 2021 03:05:26

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (17)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '99'	Nancy Tang (b) (4)	04 Jan 2021 03:05:26

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (17)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User entered '%'	System	04 Jan 2021 03:05:26

FDA-CBER-2022-1614-2895185

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (17)
Generated On: 10 Jun 2021 09:14:49
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '98' F	Nancy Tang (b) (4)	04 Jan 2021 03:05:26

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (17)
Generated On: 10 Jun 2021 09:14:49
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	04 Jan 2021 03:05:26

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (17)
Generated On: 10 Jun 2021 09:14:49
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	04 Jan 2021 03:05:26

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (17)
Generated On: 10 Jun 2021 09:14:49
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	04 Jan 2021 03:05:26

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (17)
Generated On: 10 Jun 2021 09:14:49
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	04 Jan 2021 03:05:26

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (17)
Generated On: 10 Jun 2021 09:14:49
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	04 Jan 2021 03:05:26

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (17)
Generated On: 10 Jun 2021 09:14:49
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	04 Jan 2021 03:05:26

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (17)
Generated On: 10 Jun 2021 09:14:49
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	04 Jan 2021 03:05:26

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (17)
Generated On: 10 Jun 2021 09:14:49
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	04 Jan 2021 03:05:26

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (17)
Generated On: 10 Jun 2021 09:14:49
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	04 Jan 2021 03:05:26

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (17)
Generated On: 10 Jun 2021 09:14:49
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	04 Jan 2021 03:05:26

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (17)
Generated On: 10 Jun 2021 09:14:49
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	04 Jan 2021 03:05:26

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (17)
Generated On: 10 Jun 2021 09:14:49
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	04 Jan 2021 03:05:26

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (17)
Generated On: 10 Jun 2021 09:14:49
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	04 Jan 2021 03:05:26

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (17)
Generated On: 10 Jun 2021 09:14:49
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	04 Jan 2021 03:05:26

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (17)
Generated On: 10 Jun 2021 09:14:49
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	04 Jan 2021 03:05:26

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (17)
Generated On: 10 Jun 2021 09:14:49
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	04 Jan 2021 03:05:26

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (18)
Generated On: 10 Jun 2021 09:14:49
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Day 18 (Day 18)'	Colleen McLellan (b) (4) (b) (4)	05 Jan 2021 16:34:56

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (18)
Generated On: 10 Jun 2021 09:14:49
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '4 Jan 2021'	Colleen McLellan (b) (4) (b) (4)	05 Jan 2021 16:34:56

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (18)
Generated On: 10 Jun 2021 09:14:49
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '0'	Colleen McLellan (b) (4) (b) (4)	05 Jan 2021 16:34:56

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (18)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '99'	Colleen McLellan (b) (4) (b) (4)	05 Jan 2021 16:34:56

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (18)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User entered '%'	System	05 Jan 2021 16:34:56

FDA-CBER-2022-1614-2895207

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (18)
Generated On: 10 Jun 2021 09:14:49
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '98.4' F	Colleen McLellan (b) (4) (b) (4)	05 Jan 2021 16:34:56

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (18)
Generated On: 10 Jun 2021 09:14:49
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Colleen McLellan (b) (4) (b) (4)	05 Jan 2021 16:34:56

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (18)
Generated On: 10 Jun 2021 09:14:49
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Colleen McLellan (b) (4) (b) (4)	05 Jan 2021 16:34:56

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (18)
Generated On: 10 Jun 2021 09:14:49
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Colleen McLellan (b) (4) (b) (4)	05 Jan 2021 16:34:56

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (18)
Generated On: 10 Jun 2021 09:14:49
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Colleen McLellan (b) (4) (b) (4)	05 Jan 2021 16:34:56

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (18)
Generated On: 10 Jun 2021 09:14:49
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Colleen McLellan (b) (4) (b) (4)	05 Jan 2021 16:34:56

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (18)
Generated On: 10 Jun 2021 09:14:49
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Colleen McLellan (b) (4) (b) (4)	05 Jan 2021 16:34:56

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (18)
Generated On: 10 Jun 2021 09:14:49
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Colleen McLellan (b) (4) (b) (4)	05 Jan 2021 16:34:56

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (18)
Generated On: 10 Jun 2021 09:14:49
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Colleen McLellan (b) (4) (b) (4)	05 Jan 2021 16:34:56

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (18)
Generated On: 10 Jun 2021 09:14:49
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Colleen McLellan (b) (4) (b) (4)	05 Jan 2021 16:34:56

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (18)
Generated On: 10 Jun 2021 09:14:49
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Colleen McLellan (b) (4) (b) (4)	05 Jan 2021 16:34:56

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (18)
Generated On: 10 Jun 2021 09:14:49
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Colleen McLellan (b) (4) (b) (4)	05 Jan 2021 16:34:56

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (18)
Generated On: 10 Jun 2021 09:14:49
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Colleen McLellan (b) (4) (b) (4)	05 Jan 2021 16:34:56

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (18)
Generated On: 10 Jun 2021 09:14:49
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Colleen McLellan (b) (4) (b) (4)	05 Jan 2021 16:34:56

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (18)
Generated On: 10 Jun 2021 09:14:49
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Colleen McLellan (b) (4) (b) (4)	05 Jan 2021 16:34:56

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (18)
Generated On: 10 Jun 2021 09:14:49
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Colleen McLellan (b) (4) (b) (4)	05 Jan 2021 16:34:56

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (18)
Generated On: 10 Jun 2021 09:14:49
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Colleen McLellan (b) (4) (b) (4)	05 Jan 2021 16:34:56

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (19)
Generated On: 10 Jun 2021 09:14:49
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Day 19 (Day 19)'	Nancy Tang (b) (4)	07 Jan 2021 04:01:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (19)
Generated On: 10 Jun 2021 09:14:49
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '05 Jan 2021'	Nancy Tang (b) (4)	07 Jan 2021 04:01:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (19)
Generated On: 10 Jun 2021 09:14:49
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '0'	Nancy Tang (b) (4)	07 Jan 2021 04:01:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (19)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '99'	Nancy Tang (b) (4)	07 Jan 2021 04:01:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (19)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User entered '%'	System	07 Jan 2021 04:01:33

FDA-CBER-2022-1614-2895229

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (19)
Generated On: 10 Jun 2021 09:14:49
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '98' F	Nancy Tang (b) (4)	07 Jan 2021 04:01:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (19)
Generated On: 10 Jun 2021 09:14:49
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	07 Jan 2021 04:01:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (19)
Generated On: 10 Jun 2021 09:14:49
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	07 Jan 2021 04:01:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (19)
Generated On: 10 Jun 2021 09:14:49
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	07 Jan 2021 04:01:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (19)
Generated On: 10 Jun 2021 09:14:49
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	07 Jan 2021 04:01:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (19)
Generated On: 10 Jun 2021 09:14:49
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	07 Jan 2021 04:01:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (19)
Generated On: 10 Jun 2021 09:14:49
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	07 Jan 2021 04:01:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (19)
Generated On: 10 Jun 2021 09:14:49
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	07 Jan 2021 04:01:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (19)
Generated On: 10 Jun 2021 09:14:49
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	07 Jan 2021 04:01:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (19)
Generated On: 10 Jun 2021 09:14:49
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	07 Jan 2021 04:01:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (19)
Generated On: 10 Jun 2021 09:14:49
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	07 Jan 2021 04:01:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (19)
Generated On: 10 Jun 2021 09:14:49
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	07 Jan 2021 04:01:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (19)
Generated On: 10 Jun 2021 09:14:49
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	07 Jan 2021 04:01:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (19)
Generated On: 10 Jun 2021 09:14:49
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	07 Jan 2021 04:01:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (19)
Generated On: 10 Jun 2021 09:14:49
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	07 Jan 2021 04:01:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (19)
Generated On: 10 Jun 2021 09:14:49
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	07 Jan 2021 04:01:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (19)
Generated On: 10 Jun 2021 09:14:49
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	07 Jan 2021 04:01:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (20)
Generated On: 10 Jun 2021 09:14:49
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Day 20 (Day 20)'	Nancy Tang (b) (4)	07 Jan 2021 04:02:39

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (20)
Generated On: 10 Jun 2021 09:14:49
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '06 Jan 2021'	Nancy Tang (b) (4)	07 Jan 2021 04:02:39

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (20)
Generated On: 10 Jun 2021 09:14:49
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '0'	Nancy Tang (b) (4)	07 Jan 2021 04:02:39

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (20)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '99'	Nancy Tang (b) (4)	07 Jan 2021 04:02:39

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (20)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User entered '%'	System	07 Jan 2021 04:02:39

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (20)
Generated On: 10 Jun 2021 09:14:49
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '98' F	Nancy Tang (b) (4)	07 Jan 2021 04:02:39

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (20)
Generated On: 10 Jun 2021 09:14:49
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	07 Jan 2021 04:02:39

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (20)
Generated On: 10 Jun 2021 09:14:49
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	07 Jan 2021 04:02:39

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (20)
Generated On: 10 Jun 2021 09:14:49
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	07 Jan 2021 04:02:39

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (20)
Generated On: 10 Jun 2021 09:14:49
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	07 Jan 2021 04:02:39

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (20)
Generated On: 10 Jun 2021 09:14:49
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	07 Jan 2021 04:02:39

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (20)
Generated On: 10 Jun 2021 09:14:49
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	07 Jan 2021 04:02:39

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (20)
Generated On: 10 Jun 2021 09:14:49
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	07 Jan 2021 04:02:39

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (20)
Generated On: 10 Jun 2021 09:14:49
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	07 Jan 2021 04:02:39

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (20)
Generated On: 10 Jun 2021 09:14:49
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	07 Jan 2021 04:02:39

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (20)
Generated On: 10 Jun 2021 09:14:49
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	07 Jan 2021 04:02:39

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (20)
Generated On: 10 Jun 2021 09:14:49
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	07 Jan 2021 04:02:39

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (20)
Generated On: 10 Jun 2021 09:14:49
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	07 Jan 2021 04:02:39

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (20)
Generated On: 10 Jun 2021 09:14:49
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	07 Jan 2021 04:02:39

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (20)
Generated On: 10 Jun 2021 09:14:49
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	07 Jan 2021 04:02:39

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (20)
Generated On: 10 Jun 2021 09:14:49
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	07 Jan 2021 04:02:39

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (20)
Generated On: 10 Jun 2021 09:14:49
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	07 Jan 2021 04:02:39

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (21)
Generated On: 10 Jun 2021 09:14:49
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Day 21 (Day 21)'	Nancy Tang (b) (4)	09 Jan 2021 02:55:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (21)
Generated On: 10 Jun 2021 09:14:49
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '07 Jan 2021'	Nancy Tang (b) (4)	09 Jan 2021 02:55:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (21)
Generated On: 10 Jun 2021 09:14:49
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '0'	Nancy Tang (b) (4)	09 Jan 2021 02:55:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (21)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '99'	Nancy Tang (b) (4)	09 Jan 2021 02:55:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (21)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User entered '%'	System	09 Jan 2021 02:55:33

FDA-CBER-2022-1614-2895273

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (21)
Generated On: 10 Jun 2021 09:14:49
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '98' F	Nancy Tang (b) (4)	09 Jan 2021 02:55:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (21)
Generated On: 10 Jun 2021 09:14:49
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	09 Jan 2021 02:55:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (21)
Generated On: 10 Jun 2021 09:14:49
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	09 Jan 2021 02:55:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (21)
Generated On: 10 Jun 2021 09:14:49
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	09 Jan 2021 02:55:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (21)
Generated On: 10 Jun 2021 09:14:49
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	09 Jan 2021 02:55:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (21)
Generated On: 10 Jun 2021 09:14:49
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	09 Jan 2021 02:55:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (21)
Generated On: 10 Jun 2021 09:14:49
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	09 Jan 2021 02:55:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (21)
Generated On: 10 Jun 2021 09:14:49
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	09 Jan 2021 02:55:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (21)
Generated On: 10 Jun 2021 09:14:49
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	09 Jan 2021 02:55:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (21)
Generated On: 10 Jun 2021 09:14:49
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	09 Jan 2021 02:55:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (21)
Generated On: 10 Jun 2021 09:14:49
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	09 Jan 2021 02:55:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (21)
Generated On: 10 Jun 2021 09:14:49
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	09 Jan 2021 02:55:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (21)
Generated On: 10 Jun 2021 09:14:49
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	09 Jan 2021 02:55:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (21)
Generated On: 10 Jun 2021 09:14:49
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	09 Jan 2021 02:55:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (21)
Generated On: 10 Jun 2021 09:14:49
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	09 Jan 2021 02:55:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (21)
Generated On: 10 Jun 2021 09:14:49
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	09 Jan 2021 02:55:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (21)
Generated On: 10 Jun 2021 09:14:49
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	09 Jan 2021 02:55:33

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (22)
Generated On: 10 Jun 2021 09:14:49
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Day 22 (Day 22)'	Nancy Tang (b) (4)	09 Jan 2021 02:56:24

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (22)
Generated On: 10 Jun 2021 09:14:49
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '08 Jan 2021'	Nancy Tang (b) (4)	09 Jan 2021 02:56:24

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (22)
Generated On: 10 Jun 2021 09:14:49
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '0'	Nancy Tang (b) (4)	09 Jan 2021 02:56:24

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (22)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '99'	Nancy Tang (b) (4)	09 Jan 2021 02:56:24

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (22)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User entered '%'	System	09 Jan 2021 02:56:24

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (22)
Generated On: 10 Jun 2021 09:14:49
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '98' F	Nancy Tang (b) (4)	09 Jan 2021 02:56:24

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (22)
Generated On: 10 Jun 2021 09:14:49
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	09 Jan 2021 02:56:24

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (22)
Generated On: 10 Jun 2021 09:14:49
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	09 Jan 2021 02:56:24

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (22)
Generated On: 10 Jun 2021 09:14:49
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	09 Jan 2021 02:56:24

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (22)
Generated On: 10 Jun 2021 09:14:49
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	09 Jan 2021 02:56:24

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (22)
Generated On: 10 Jun 2021 09:14:49
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	09 Jan 2021 02:56:24

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (22)
Generated On: 10 Jun 2021 09:14:49
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	09 Jan 2021 02:56:24

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (22)
Generated On: 10 Jun 2021 09:14:49
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	09 Jan 2021 02:56:24

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (22)
Generated On: 10 Jun 2021 09:14:49
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	09 Jan 2021 02:56:24

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (22)
Generated On: 10 Jun 2021 09:14:49
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	09 Jan 2021 02:56:24

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (22)
Generated On: 10 Jun 2021 09:14:49
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	09 Jan 2021 02:56:24

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (22)
Generated On: 10 Jun 2021 09:14:49
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	09 Jan 2021 02:56:24

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (22)
Generated On: 10 Jun 2021 09:14:49
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	09 Jan 2021 02:56:24

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (22)
Generated On: 10 Jun 2021 09:14:49
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	09 Jan 2021 02:56:24

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (22)
Generated On: 10 Jun 2021 09:14:49
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	09 Jan 2021 02:56:24

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (22)
Generated On: 10 Jun 2021 09:14:49
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	09 Jan 2021 02:56:24

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (22)
Generated On: 10 Jun 2021 09:14:49
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	09 Jan 2021 02:56:24

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (23)
Generated On: 10 Jun 2021 09:14:49
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Day 23 (Day 23)'	Nancy Tang (b) (4)	10 Jan 2021 01:03:31

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (23)
Generated On: 10 Jun 2021 09:14:49
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '09 Jan 2021'	Nancy Tang (b) (4)	10 Jan 2021 01:03:31

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (23)
Generated On: 10 Jun 2021 09:14:49
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '0'	Nancy Tang (b) (4)	10 Jan 2021 01:03:31

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (23)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '99'	Nancy Tang (b) (4)	10 Jan 2021 01:03:31

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (23)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User entered '%'	System	10 Jan 2021 01:03:31

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (23)
Generated On: 10 Jun 2021 09:14:49
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '98.2' F	Nancy Tang (b) (4)	10 Jan 2021 01:03:31

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (23)
Generated On: 10 Jun 2021 09:14:49
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	10 Jan 2021 01:03:31

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (23)
Generated On: 10 Jun 2021 09:14:49
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	10 Jan 2021 01:03:31

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (23)
Generated On: 10 Jun 2021 09:14:49
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	10 Jan 2021 01:03:31

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (23)
Generated On: 10 Jun 2021 09:14:49
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	10 Jan 2021 01:03:31

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (23)
Generated On: 10 Jun 2021 09:14:49
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	10 Jan 2021 01:03:31

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (23)
Generated On: 10 Jun 2021 09:14:49
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	10 Jan 2021 01:03:31

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (23)
Generated On: 10 Jun 2021 09:14:49
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	10 Jan 2021 01:03:31

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (23)
Generated On: 10 Jun 2021 09:14:49
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	10 Jan 2021 01:03:31

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (23)
Generated On: 10 Jun 2021 09:14:49
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	10 Jan 2021 01:03:31

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (23)
Generated On: 10 Jun 2021 09:14:49
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	10 Jan 2021 01:03:31

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (23)
Generated On: 10 Jun 2021 09:14:49
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	10 Jan 2021 01:03:31

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (23)
Generated On: 10 Jun 2021 09:14:49
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	10 Jan 2021 01:03:31

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (23)
Generated On: 10 Jun 2021 09:14:49
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	10 Jan 2021 01:03:31

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (23)
Generated On: 10 Jun 2021 09:14:49
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	10 Jan 2021 01:03:31

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (23)
Generated On: 10 Jun 2021 09:14:49
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	10 Jan 2021 01:03:31

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (23)
Generated On: 10 Jun 2021 09:14:49
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	10 Jan 2021 01:03:31

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (24)
Generated On: 10 Jun 2021 09:14:49
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Day 24 (Day 24)'	Nancy Tang (b) (4)	10 Jan 2021 20:59:16

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (24)
Generated On: 10 Jun 2021 09:14:49
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '10 Jan 2021'	Nancy Tang (b) (4)	10 Jan 2021 20:59:16

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (24)
Generated On: 10 Jun 2021 09:14:49
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '0'	Nancy Tang (b) (4)	10 Jan 2021 20:59:16

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (24)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '99'	Nancy Tang (b) (4)	10 Jan 2021 20:59:16

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (24)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User entered '%'	System	10 Jan 2021 20:59:16

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (24)
Generated On: 10 Jun 2021 09:14:49
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '98' F	Nancy Tang (b) (4)	10 Jan 2021 20:59:16

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (24)
Generated On: 10 Jun 2021 09:14:49
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	10 Jan 2021 20:59:16

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (24)
Generated On: 10 Jun 2021 09:14:49
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	10 Jan 2021 20:59:16

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (24)
Generated On: 10 Jun 2021 09:14:49
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	10 Jan 2021 20:59:16

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (24)
Generated On: 10 Jun 2021 09:14:49
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	10 Jan 2021 20:59:16

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (24)
Generated On: 10 Jun 2021 09:14:49
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	10 Jan 2021 20:59:16

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (24)
Generated On: 10 Jun 2021 09:14:49
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	10 Jan 2021 20:59:16

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (24)
Generated On: 10 Jun 2021 09:14:49
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	10 Jan 2021 20:59:16

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (24)
Generated On: 10 Jun 2021 09:14:49
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'Mild (Mild)'	Nancy Tang (b) (4)	10 Jan 2021 20:59:16

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (24)
Generated On: 10 Jun 2021 09:14:49
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	10 Jan 2021 20:59:16

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (24)
Generated On: 10 Jun 2021 09:14:49
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	10 Jan 2021 20:59:16

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (24)
Generated On: 10 Jun 2021 09:14:49
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	10 Jan 2021 20:59:16

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (24)
Generated On: 10 Jun 2021 09:14:49
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	10 Jan 2021 20:59:16

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (24)
Generated On: 10 Jun 2021 09:14:49
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	10 Jan 2021 20:59:16

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (24)
Generated On: 10 Jun 2021 09:14:49
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	10 Jan 2021 20:59:16

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (24)
Generated On: 10 Jun 2021 09:14:49
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	10 Jan 2021 20:59:16

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (24)
Generated On: 10 Jun 2021 09:14:49
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	10 Jan 2021 20:59:16

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (25)
Generated On: 10 Jun 2021 09:14:49
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Day 25 (Day 25)'	Nancy Tang (b) (4)	11 Jan 2021 22:45:42

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (25)
Generated On: 10 Jun 2021 09:14:49
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '11 Jan 2021'	Nancy Tang (b) (4)	11 Jan 2021 22:45:42

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (25)
Generated On: 10 Jun 2021 09:14:49
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '0'	Nancy Tang (b) (4)	11 Jan 2021 22:45:42

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (25)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '99'	Nancy Tang (b) (4)	11 Jan 2021 22:45:42

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (25)
Generated On: 10 Jun 2021 09:14:49
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User entered '%'	System	11 Jan 2021 22:45:42

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (25)
Generated On: 10 Jun 2021 09:14:49
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered '98' F	Nancy Tang (b) (4)	11 Jan 2021 22:45:42

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (25)
Generated On: 10 Jun 2021 09:14:49
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	11 Jan 2021 22:45:42

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (25)
Generated On: 10 Jun 2021 09:14:49
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	11 Jan 2021 22:45:42

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (25)
Generated On: 10 Jun 2021 09:14:49
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	11 Jan 2021 22:45:42

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (25)
Generated On: 10 Jun 2021 09:14:49
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	11 Jan 2021 22:45:42

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (25)
Generated On: 10 Jun 2021 09:14:49
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	11 Jan 2021 22:45:42

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (25)
Generated On: 10 Jun 2021 09:14:49
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	11 Jan 2021 22:45:42

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (25)
Generated On: 10 Jun 2021 09:14:49
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	11 Jan 2021 22:45:42

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (25)
Generated On: 10 Jun 2021 09:14:49
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	11 Jan 2021 22:45:42

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (25)
Generated On: 10 Jun 2021 09:14:49
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	11 Jan 2021 22:45:42

FDA-CBER-2022-1614-2895371

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (25)
Generated On: 10 Jun 2021 09:14:49
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	11 Jan 2021 22:45:42

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (25)
Generated On: 10 Jun 2021 09:14:49
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	11 Jan 2021 22:45:42

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (25)
Generated On: 10 Jun 2021 09:14:49
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	11 Jan 2021 22:45:42

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (25)
Generated On: 10 Jun 2021 09:14:49
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	11 Jan 2021 22:45:42

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (25)
Generated On: 10 Jun 2021 09:14:49
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	11 Jan 2021 22:45:42

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (25)
Generated On: 10 Jun 2021 09:14:49
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	11 Jan 2021 22:45:42

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Symptom Log (25)
Generated On: 10 Jun 2021 09:14:49
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:36:28
User entered 'None (None)'	Nancy Tang (b) (4)	11 Jan 2021 22:45:42

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: COVID Diagnostic Test
Generated On: 10 Jun 2021 09:14:49
Date of Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:56
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:19:17
User entered '22 Dec 2020'	Nancy Tang (b) (4)	24 Dec 2020 22:36:28

FDA-CBER-2022-1614-2895379

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: COVID Diagnostic Test
Generated On: 10 Jun 2021 09:14:49
Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:56
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:19:19
User entered 'Yes (Y)'	Nancy Tang (b) (4)	24 Dec 2020 22:36:28

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: COVID Diagnostic Test
Generated On: 10 Jun 2021 09:14:49
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:56
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	01 Feb 2021 03:51:53
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:19:15
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'ae added' (Site from System).	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:26:54
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	24 Dec 2020 22:36:28
User entered 'Yes (Y)'	Nancy Tang (b) (4)	24 Dec 2020 22:36:28

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: COVID Diagnostic Test
Generated On: 10 Jun 2021 09:14:49
Date of Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:56
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:20:15
User entered '22 Dec 2020'	Nancy Tang (b) (4)	24 Dec 2020 22:36:28

FDA-CBER-2022-1614-2895382

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: COVID Diagnostic Test
Generated On: 10 Jun 2021 09:14:49
Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:56
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:20:15
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Nancy Tang (b) (4)	24 Dec 2020 22:36:28

FDA-CBER-2022-1614-2895383

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: COVID Diagnostic Test
Generated On: 10 Jun 2021 09:14:49
Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:56
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:20:15
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:36:28

FDA-CBER-2022-1614-2895384

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: COVID Diagnostic Test
Generated On: 10 Jun 2021 09:14:49
Was this diagnostic test performed at a lab other than the Study Central Lab?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:56
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:20:15
User entered 'No (N)'	Nancy Tang (b) (4)	24 Dec 2020 22:36:28

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: COVID Diagnostic Test
Generated On: 10 Jun 2021 09:14:49
Lab/ Institution Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:56
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:20:15
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:36:28

FDA-CBER-2022-1614-2895386

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: COVID Diagnostic Test
Generated On: 10 Jun 2021 09:14:49
CLIA Certified?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:56
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:20:15
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:36:28

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: COVID Diagnostic Test
Generated On: 10 Jun 2021 09:14:49
COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:52:56
User entered '1'	System	24 Dec 2020 22:36:28

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered 'No (N)'	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

FDA-CBER-2022-1614-2895390

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

FDA-CBER-2022-1614-2895391

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
Respiratory Rate

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
Did the subject have Heart Rate ≥ 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered 'No (N)'	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

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US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
Heart Rate

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered 'No (N)'	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

FDA-CBER-2022-1614-2895398

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

FDA-CBER-2022-1614-2895399

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
Oxygen Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered 'No (N)'	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

FDA-CBER-2022-1614-2895402

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
PaO2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered 'No (N)'	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

FDA-CBER-2022-1614-2895406

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 21:21:07
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Dec 2020 22:51:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Dec 2020 22:51:27
User entered 'No (N)' reason for change: Data Entry Error	Nancy Tang (b) (4)	24 Dec 2020 22:51:27
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Dec 2020 22:51:20
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
High-Flow Oxygen?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered 'No (N)'	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

FDA-CBER-2022-1614-2895410

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

FDA-CBER-2022-1614-2895411

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
Non-Invasive Ventilation?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered 'No (N)'	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

FDA-CBER-2022-1614-2895413

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

FDA-CBER-2022-1614-2895414

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
Mechanical Ventilation?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered 'No (N)'	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

FDA-CBER-2022-1614-2895416

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

FDA-CBER-2022-1614-2895417

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
ECMO?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered 'No (N)'	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

FDA-CBER-2022-1614-2895419

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

FDA-CBER-2022-1614-2895420

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered 'No (N)'	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

FDA-CBER-2022-1614-2895421

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

FDA-CBER-2022-1614-2895422

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

FDA-CBER-2022-1614-2895423

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
Evidence of Shock Requires Vasopressors

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered 'No (N)'	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

FDA-CBER-2022-1614-2895425

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
Acute Renal Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered 'No (N)'	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

FDA-CBER-2022-1614-2895428

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
Hepatic Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered 'No (N)'	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

FDA-CBER-2022-1614-2895430

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
Neurologic Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered 'No (N)'	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

FDA-CBER-2022-1614-2895432

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
Clinical Evidence

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered 'No (N)'	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

FDA-CBER-2022-1614-2895433

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
Date of Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
Radiographical Evidence

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered 'No (N)'	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
Date of Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

FDA-CBER-2022-1614-2895436

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
Admission to an intensive care unit due to SARS-CoV-2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered 'No (N)'	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

FDA-CBER-2022-1614-2895438

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 09:14:49
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:07
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:51:20

FDA-CBER-2022-1614-2895439

US3642086
Folder: Covid-19 Assessment 22 Dec 2020
Form: Generate Next COVID-19 Assessment
Generated On: 10 Jun 2021 09:14:49
Generate Next COVID-19 Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:53:16
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:21:11
User entered 'No (N)' reason for change: Data Entry Error	Nancy Tang (b) (4)	24 Dec 2020 22:52:04
User entered 'Yes (Y)'	Nancy Tang (b) (4)	24 Dec 2020 22:51:44

US3642086
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 10 Jun 2021 09:14:49
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:35:50
User accepted default value 'Day 3 (Day 3)'	Nancy Tang (b) (4)	21 Jan 2021 00:03:38

US3642086
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 10 Jun 2021 09:14:49
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:35:50
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:39:08
User entered 'Yes (Y)'	Nancy Tang (b) (4)	21 Jan 2021 00:03:38

FDA-CBER-2022-1614-2895442

US3642086
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 10 Jun 2021 09:14:49
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:35:50
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:39:08
User entered '24 Dec 2020'	Nancy Tang (b) (4)	21 Jan 2021 00:03:38

US3642086
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 10 Jun 2021 09:14:49
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:35:50
User accepted default value 'Day 5 (Day 5)'	Nancy Tang (b) (4)	21 Jan 2021 00:03:38

US3642086
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 10 Jun 2021 09:14:49
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:35:50
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:39:08
User entered 'Yes (Y)'	Nancy Tang (b) (4)	21 Jan 2021 00:03:38

US3642086
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 10 Jun 2021 09:14:49
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:35:50
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:41:13
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:39:08
User entered '26 Dec 2020'	Nancy Tang (b) (4)	21 Jan 2021 00:03:38

US3642086
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 10 Jun 2021 09:14:49
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:35:50
User accepted default value 'Day 7 (Day 7)'	Nancy Tang (b) (4)	21 Jan 2021 00:03:38

US3642086
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 10 Jun 2021 09:14:49
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:35:50
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:39:08
User entered 'Yes (Y)'	Nancy Tang (b) (4)	21 Jan 2021 00:03:38

FDA-CBER-2022-1614-2895448

US3642086
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 10 Jun 2021 09:14:49
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:35:50
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:39:08
User entered '28 Dec 2020'	Nancy Tang (b) (4)	21 Jan 2021 00:03:38

US3642086
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 10 Jun 2021 09:14:49
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:35:50
User accepted default value 'Day 9 (Day 9)'	Nancy Tang (b) (4)	21 Jan 2021 00:03:38

US3642086
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 10 Jun 2021 09:14:49
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:35:50
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:39:08
User entered 'Yes (Y)'	Nancy Tang (b) (4)	21 Jan 2021 00:03:38

US3642086
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 10 Jun 2021 09:14:49
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:35:50
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:41:13
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:39:08
User entered '30 Dec 2020'	Nancy Tang (b) (4)	21 Jan 2021 00:03:38

US3642086
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 10 Jun 2021 09:14:49
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:35:50
User accepted default value 'Day 14 (Day 14)'	Nancy Tang (b) (4)	21 Jan 2021 00:03:38

US3642086
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 10 Jun 2021 09:14:49
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:35:50
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:39:08
User entered 'Yes (Y)'	Nancy Tang (b) (4)	21 Jan 2021 00:03:38

US3642086
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 10 Jun 2021 09:14:49
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:35:50
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:41:13
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04JAN2021 is recorded under Illness Visit Day 14 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Feb 2021 18:05:47
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04JAN2021 is recorded under Illness Visit Day 14 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 06:31:00
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:39:08
User entered '04 Jan 2021'	Nancy Tang (b) (4)	21 Jan 2021 00:03:38

US3642086
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 10 Jun 2021 09:14:49
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:35:50
User accepted default value 'Day 21 (Day 21)'	Nancy Tang (b) (4)	21 Jan 2021 00:03:38

US3642086
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 10 Jun 2021 09:14:49
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:35:50
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:39:08
User entered 'Yes (Y)'	Nancy Tang (b) (4)	21 Jan 2021 00:03:38

US3642086
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 10 Jun 2021 09:14:49
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:35:50
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:41:13
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11JAN2021 is recorded under Illness Visit Day 21 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' canceled (Site from DM).	(b) (4), (b) (6) (b) (4)	21 Feb 2021 18:05:52
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11JAN2021 is recorded under Illness Visit Day 21 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 06:40:34
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:39:08
User entered '11 Jan 2021'	Nancy Tang (b) (4)	21 Jan 2021 00:03:38

US3642086
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 10 Jun 2021 09:14:49
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:35:50
User accepted default value 'Day 28 (Day 28)'	Nancy Tang (b) (4)	21 Jan 2021 00:03:38

US3642086
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 10 Jun 2021 09:14:49
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:35:50
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:39:08
User entered 'Yes (Y)'	Nancy Tang (b) (4)	21 Jan 2021 00:03:38

US3642086
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 10 Jun 2021 09:14:49
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:35:50
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:41:13
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20JAN2021 is recorded under Illness Visit Day 28 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Feb 2021 18:05:57
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20JAN2021 is recorded under Illness Visit Day 28 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 06:40:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:39:08
User entered '20 Jan 2021'	Nancy Tang (b) (4)	21 Jan 2021 00:03:38

FDA-CBER-2022-1614-2895461

US3642086
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:36:29
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:10:55
User entered 'Yes (Y)'	Nancy Tang (b) (4)	24 Dec 2020 22:48:59

US3642086
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:36:29
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:10:55
User entered '22 Dec 2020'	Nancy Tang (b) (4)	24 Dec 2020 22:48:59

US3642086
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:36:29
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:10:55
User entered 'Clinic (Clinic)'	Nancy Tang (b) (4)	24 Dec 2020 22:48:59

FDA-CBER-2022-1614-2895464

US3642086
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:36:29
User entered 'SICKD1'	System	24 Dec 2020 22:48:59

FDA-CBER-2022-1614-2895465

US3642086
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:36:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:12:56
User entered 'Yes (Y)'	Nancy Tang (b) (4)	24 Dec 2020 22:49:58

FDA-CBER-2022-1614-2895466

US3642086
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:36:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:12:56
User entered '22 Dec 2020'	Nancy Tang (b) (4)	24 Dec 2020 22:49:58

FDA-CBER-2022-1614-2895467

US3642086
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:36:42
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:12:56
User entered '10:37'	Nancy Tang (b) (4)	24 Dec 2020 22:49:58

FDA-CBER-2022-1614-2895468

US3642086
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:36:42
User entered '22 Dec 2020 10:37'	System	24 Dec 2020 22:49:58

FDA-CBER-2022-1614-2895469

US3642086
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:36:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:12:56
User entered missing code ND - Not Done.	Nancy Tang (b) (4)	24 Dec 2020 22:49:58
DataPoint set to visible.	System	24 Dec 2020 22:48:59

FDA-CBER-2022-1614-2895470

US3642086
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:36:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:12:56
User entered missing code ND - Not Done.	Nancy Tang (b) (4)	24 Dec 2020 22:49:58
DataPoint set to visible.	System	24 Dec 2020 22:48:59

US3642086
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:36:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:12:56
User entered '98.5' F	Nancy Tang (b) (4)	24 Dec 2020 22:49:58

US3642086
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:36:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:12:56
User entered 'Oral (Oral)'	Nancy Tang (b) (4)	24 Dec 2020 22:49:58

US3642086
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:36:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:12:56
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:49:58

US3642086
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:36:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:12:56
User entered '78'	Nancy Tang (b) (4)	24 Dec 2020 22:49:58

US3642086
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:36:42
User entered 'bpm'	System	24 Dec 2020 22:49:58

FDA-CBER-2022-1614-2895476

US3642086
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:36:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:12:56
User entered '18'	Nancy Tang (b) (4)	24 Dec 2020 22:49:58

US3642086
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:36:42
User entered 'breaths/min'	System	24 Dec 2020 22:49:58

US3642086
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:36:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 21:12:56
User entered missing code ND - Not Done.	Nancy Tang (b) (4)	24 Dec 2020 22:49:58

FDA-CBER-2022-1614-2895479

US3642086
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:36:42
User entered 'mmHg'	System	24 Dec 2020 22:49:58

FDA-CBER-2022-1614-2895480

US3642086
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:36:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 21:12:56
User entered missing code ND - Not Done.	Nancy Tang (b) (4)	24 Dec 2020 22:49:58

FDA-CBER-2022-1614-2895481

US3642086
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:36:42
User entered 'mmHg'	System	24 Dec 2020 22:49:58

FDA-CBER-2022-1614-2895482

US3642086
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:36:42

FDA-CBER-2022-1614-2895483

US3642086
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:36:42

FDA-CBER-2022-1614-2895484

US3642086
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:14:49
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:36:56
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:13:00
User entered 'Yes (Y)'	Nancy Tang (b) (4)	24 Dec 2020 22:50:16

US3642086
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:14:49
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:36:56
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:13:00
User entered '22 Dec 2020'	Nancy Tang (b) (4)	24 Dec 2020 22:50:16

US3642086
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 10 Jun 2021 09:14:49
Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:37:10
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:18:39
User entered 'Yes (Y)'	Nancy Tang (b) (4)	24 Dec 2020 22:50:25

US3642086
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 10 Jun 2021 09:14:49
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:37:10
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:18:39
User entered '22 Dec 2020'	Nancy Tang (b) (4)	24 Dec 2020 22:50:25

US3642086
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:39:41
User entered 'Yes (Y)'	Nancy Tang (b) (4)	20 Jan 2021 23:59:16

US3642086
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:39:41
User closed query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	20 Jan 2021 23:59:22
User entered '20 Jan 2021' reason for change: Data Entry Error	Nancy Tang (b) (4)	20 Jan 2021 23:59:22
User opened query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	20 Jan 2021 23:59:16
User entered '20 Jan 2020'	Nancy Tang (b) (4)	20 Jan 2021 23:59:16

US3642086
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:39:41
User entered 'Clinic (Clinic)'	Nancy Tang (b) (4)	20 Jan 2021 23:59:16

US3642086
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:28
User entered 'SICKD28'	System	20 Jan 2021 23:59:16

FDA-CBER-2022-1614-2895492

US3642086
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:40:13
User entered 'Yes (Y)'	Nancy Tang (b) (4)	21 Jan 2021 00:06:55

US3642086
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:40:13
User entered '20 Jan 2021'	Nancy Tang (b) (4)	21 Jan 2021 00:06:55

FDA-CBER-2022-1614-2895494

US3642086
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:40:13
User entered '14:20'	Nancy Tang (b) (4)	21 Jan 2021 00:06:55

FDA-CBER-2022-1614-2895495

US3642086
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:28
User entered '20 Jan 2021 14:20'	System	21 Jan 2021 00:06:55

FDA-CBER-2022-1614-2895496

US3642086
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:40:13
User entered missing code ND - Not Done.	Nancy Tang (b) (4)	21 Jan 2021 00:06:55
DataPoint set to visible.	System	20 Jan 2021 23:59:16

US3642086
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 21:40:13
User entered missing code ND - Not Done.	Nancy Tang (b) (4)	21 Jan 2021 00:06:55
DataPoint set to visible.	System	20 Jan 2021 23:59:16

US3642086
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:40:13
User entered '98.3' F	Nancy Tang (b) (4)	21 Jan 2021 00:06:55

US3642086
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:40:13
User entered 'Oral (Oral)'	Nancy Tang (b) (4)	21 Jan 2021 00:06:55

US3642086
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:40:13
User entered empty.	Nancy Tang (b) (4)	21 Jan 2021 00:06:55

US3642086
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:40:13
User entered '81'	Nancy Tang (b) (4)	21 Jan 2021 00:06:55

US3642086
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:28
User entered 'bpm'	System	21 Jan 2021 00:06:55

US3642086
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:40:13
User entered '17'	Nancy Tang (b) (4)	21 Jan 2021 00:06:55

US3642086
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:28
User entered 'breaths/min'	System	21 Jan 2021 00:06:55

US3642086
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:40:13
User entered '121'	Nancy Tang (b) (4)	21 Jan 2021 00:06:55

US3642086
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:28
User entered 'mmHg'	System	21 Jan 2021 00:06:55

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US3642086
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:40:13
User entered '72'	Nancy Tang (b) (4)	21 Jan 2021 00:06:55

US3642086
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:28
User entered 'mmHg'	System	21 Jan 2021 00:06:55

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US3642086
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:28

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US3642086
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:28

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US3642086
Folder: Convalescence Visit Day 28 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:14:49
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:28
User closed query 'Convalescence Visit Day 28 and Participant Decision Visit / OL-D1 are both dated 20Jan2021. However, the data on the Physical Examination forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile. Thank you' (Site from DM).		15 Apr 2021 16:38:05
Query 'Convalescence Visit Day 28 and Participant Decision Visit / OL-D1 are both dated 20Jan2021. However, the data on the Physical Examination forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile. Thank you' answered with 'the date of the physical exam has been added to the ol day 1 visit. the data now match.' (Site from DM).	Megan Loughran (b) (4) (b) (4)	14 Apr 2021 16:06:43
User opened query 'Convalescence Visit Day 28 and Participant Decision Visit / OL-D1 are both dated 20Jan2021. However, the data on the Physical Examination forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile. Thank you' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 20:40:38
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:40:21
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	21 Jan 2021 00:10:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Nancy Tang (b) (4)	21 Jan 2021 00:10:53
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	21 Jan 2021 00:10:37
User entered 'No (N)' reason for change: Data Entry Error	Nancy Tang (b) (4)	21 Jan 2021 00:10:37
User entered 'Yes (Y)'	Nancy Tang (b) (4)	20 Jan 2021 23:59:47

US3642086
Folder: Convalescence Visit Day 28 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:14:49
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:40:21
User entered '20 Jan 2021'	Nancy Tang (b) (4)	20 Jan 2021 23:59:47

US3642086
Folder: Convalescence Visit Day 28 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 10 Jun 2021 09:14:49
Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:40:27
User entered 'Yes (Y)'	Nancy Tang (b) (4)	20 Jan 2021 23:59:58

US3642086
Folder: Convalescence Visit Day 28 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 10 Jun 2021 09:14:49
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:40:27
User entered '20 Jan 2021'	Nancy Tang (b) (4)	20 Jan 2021 23:59:58

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:02:11
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered 'Yes (Y)'	Nancy Tang (b) (4)	21 Jan 2021 00:07:18

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:02:11
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered '20 Jan 2021'	Nancy Tang (b) (4)	21 Jan 2021 00:07:18

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:02:11
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered 'Clinic (Clinic)'	Nancy Tang (b) (4)	21 Jan 2021 00:07:18

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered 'UNBLND_DECIDE'	System	21 Jan 2021 00:07:18

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US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:14:49
Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:04:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered '20 Jan 2021'	Son Do (b) (4)	21 Jan 2021 16:58:19

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US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:14:49
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Mar 2021 02:13:36
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:26:41

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:14:49
Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:04:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered 'Yes (Y)'	Son Do (b) (4)	21 Jan 2021 16:58:19

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:14:49
Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Mar 2021 02:13:36
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:26:41

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:14:49
Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:04:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 11:49:21
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered with 'Data are correct. Subject unblinding occurred prior to date of consent form. PD reported. ' (Site from System).	Colleen McLellan (b) (4) (b) (4)	26 Jan 2021 22:58:42
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	21 Jan 2021 16:58:19
User entered '08 Jan 2021'	Son Do (b) (4)	21 Jan 2021 16:58:19

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US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:14:49
Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:04:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered 'Placebo (Placebo)'	Son Do (b) (4)	21 Jan 2021 16:58:19

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US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:14:49
Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:04:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered 'Placebo (Placebo)'	Son Do (b) (4)	21 Jan 2021 16:58:19

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:14:49
Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:04:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered 'Placebo (Placebo)'	Son Do (b) (4)	21 Jan 2021 16:58:19

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:14:49
Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:04:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered 'Yes (Y)'	Son Do (b) (4)	21 Jan 2021 16:58:19

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US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:14:49
Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered '1'	System	21 Jan 2021 16:58:19

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US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:14:49
Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered '1'	System	21 Jan 2021 16:58:19

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US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:14:49
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:03:31
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered missing code ND - Not Done.	Son Do (b) (4)	21 Jan 2021 16:59:11

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US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:14:49
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:03:31
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered missing code ND - Not Done.	Son Do (b) (4)	21 Jan 2021 16:59:11

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US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:14:49
BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered empty.	System	21 Jan 2021 16:59:11
DataPoint set to visible.	System	21 Jan 2021 16:58:19

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:14:49
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:03:31
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered missing code ND - Not Done.	Son Do (b) (4)	21 Jan 2021 16:59:11

FDA-CBER-2022-1614-2895534

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:14:49
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:03:31
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered missing code ND - Not Done.	Son Do (b) (4)	21 Jan 2021 16:59:11

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US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:14:49
BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered empty.	System	21 Jan 2021 16:59:11
DataPoint set to visible.	System	21 Jan 2021 16:58:19

FDA-CBER-2022-1614-2895536

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User accepted default value 'Pre-Dose (PREDOSE)'	Son Do (b) (4)	21 Jan 2021 16:59:11

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US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:03:31
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered 'Yes (Y)'	Son Do (b) (4)	21 Jan 2021 16:59:11

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US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:03:31
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered '20 Jan 2021'	Son Do (b) (4)	21 Jan 2021 16:59:11

FDA-CBER-2022-1614-2895539

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:03:31
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered '14:20'	Son Do (b) (4)	21 Jan 2021 16:59:11

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US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered '20 Jan 2021 14:20'	System	21 Jan 2021 16:59:11

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:03:31
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered '98.3' F	Son Do (b) (4)	21 Jan 2021 16:59:11

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:03:31
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered 'Oral (Oral)'	Son Do (b) (4)	21 Jan 2021 16:59:11

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US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:03:31
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered empty.	Son Do (b) (4)	21 Jan 2021 16:59:11

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:03:31
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered '81'	Son Do (b) (4)	21 Jan 2021 16:59:11

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered 'bpm'	System	21 Jan 2021 16:59:11

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US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:03:31
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered '17'	Son Do (b) (4)	21 Jan 2021 16:59:11

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered 'breaths/min'	System	21 Jan 2021 16:59:11

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:03:31
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered '127'	Son Do (b) (4)	21 Jan 2021 16:59:11

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered 'mmHg'	System	21 Jan 2021 16:59:11

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US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:03:31
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered '72'	Son Do (b) (4)	21 Jan 2021 16:59:11

FDA-CBER-2022-1614-2895551

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered 'mmHg'	System	21 Jan 2021 16:59:11

FDA-CBER-2022-1614-2895552

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:14:49
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:03:31
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered missing code ND - Not Done.	Son Do (b) (4)	21 Jan 2021 16:59:11

FDA-CBER-2022-1614-2895553

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:14:49
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:03:31
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered missing code ND - Not Done.	Son Do (b) (4)	21 Jan 2021 16:59:11

FDA-CBER-2022-1614-2895554

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:14:49
BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered empty.	System	21 Jan 2021 16:59:11
DataPoint set to visible.	System	21 Jan 2021 16:58:19

FDA-CBER-2022-1614-2895555

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User accepted default value 'Post-Dose (POSTDOSE)'	Son Do (b) (4)	21 Jan 2021 16:59:11

FDA-CBER-2022-1614-2895556

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:03:31
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered 'Yes (Y)'	Son Do (b) (4)	21 Jan 2021 16:59:11

FDA-CBER-2022-1614-2895557

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:03:31
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered '20 Jan 2021'	Son Do (b) (4)	21 Jan 2021 16:59:11

FDA-CBER-2022-1614-2895558

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:03:31
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered '16:08'	Son Do (b) (4)	21 Jan 2021 16:59:11

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered '20 Jan 2021 16:08'	System	21 Jan 2021 16:59:11

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:03:31
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered '98' F	Son Do (b) (4)	21 Jan 2021 16:59:11

FDA-CBER-2022-1614-2895561

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:03:31
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered 'Oral (Oral)'	Son Do (b) (4)	21 Jan 2021 16:59:11

FDA-CBER-2022-1614-2895562

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:03:31
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered empty.	Son Do (b) (4)	21 Jan 2021 16:59:11

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:03:31
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered '76'	Son Do (b) (4)	21 Jan 2021 16:59:11

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered 'bpm'	System	21 Jan 2021 16:59:11

FDA-CBER-2022-1614-2895565

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:03:31
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered '18'	Son Do (b) (4)	21 Jan 2021 16:59:11

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered 'breaths/min'	System	21 Jan 2021 16:59:11

FDA-CBER-2022-1614-2895567

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:03:31
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered '113'	Son Do (b) (4)	21 Jan 2021 16:59:11

FDA-CBER-2022-1614-2895568

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered 'mmHg'	System	21 Jan 2021 16:59:11

FDA-CBER-2022-1614-2895569

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:03:31
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered '75'	Son Do (b) (4)	21 Jan 2021 16:59:11

FDA-CBER-2022-1614-2895570

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered 'mmHg'	System	21 Jan 2021 16:59:11

FDA-CBER-2022-1614-2895571

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:14:49
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		20 Apr 2021 17:02:20
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	19 Apr 2021 18:02:04
DataPoint Un-verified.	Megan Loughran (b) (4) (b) (4)	14 Apr 2021 16:06:09
Signature has been broken.	Megan Loughran (b) (4) (b) (4)	14 Apr 2021 16:06:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	14 Apr 2021 16:06:09
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:02:16
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered 'No (N)'	Son Do (b) (4)	21 Jan 2021 16:59:17

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:14:49
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		20 Apr 2021 17:02:20
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	19 Apr 2021 18:02:04
DataPoint Un-verified.	Megan Loughran (b) (4) (b) (4)	14 Apr 2021 16:06:09
Signature has been broken.	Megan Loughran (b) (4) (b) (4)	14 Apr 2021 16:06:09
User entered '20 Jan 2021' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	14 Apr 2021 16:06:09
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:02:16
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered empty.	Son Do (b) (4)	21 Jan 2021 16:59:17

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:03:39
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered 'Yes (Y)'	Son Do (b) (4)	21 Jan 2021 16:59:31

FDA-CBER-2022-1614-2895574

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:03:39
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered empty.	Son Do (b) (4)	21 Jan 2021 16:59:31

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:03:39
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
User entered empty.	Son Do (b) (4)	21 Jan 2021 16:59:31

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered 'mRNA-1273'	System	21 Jan 2021 16:59:31
DataPoint set to visible.	System	21 Jan 2021 16:58:19

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:03:39
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered '20 Jan 2021'	Son Do (b) (4)	21 Jan 2021 16:59:31

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:03:39
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered '15:25'	Son Do (b) (4)	21 Jan 2021 16:59:31

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered '20 Jan 2021 15:25'	System	21 Jan 2021 16:59:31

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US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:03:39
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered 'Left Arm (LEFT ARM)'	Son Do (b) (4)	21 Jan 2021 16:59:31

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US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:03:39
User entered 'ONCE'	System	21 Jan 2021 16:59:31

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered 'INTRAMUSCULAR'	System	21 Jan 2021 16:59:31

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:14:49
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:03:43
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered 'Yes (Y)'	Nancy Tang (b) (4)	21 Jan 2021 00:08:20

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US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:14:49
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:03:43
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered '20 Jan 2021'	Nancy Tang (b) (4)	21 Jan 2021 00:08:20

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:14:49
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:03:43
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered '15:10'	Nancy Tang (b) (4)	21 Jan 2021 00:08:20

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:14:49
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered '20 Jan 2021 15:10'	System	21 Jan 2021 00:08:20

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 10 Jun 2021 09:14:49
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:03:49
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Yes (Y)'	Nancy Tang (b) (4)	21 Jan 2021 00:08:01

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 10 Jun 2021 09:14:49
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:03:49
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '20 Jan 2021'	Nancy Tang (b) (4)	21 Jan 2021 00:08:01

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 10 Jun 2021 09:14:49
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:03:49
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '15:07'	Nancy Tang (b) (4)	21 Jan 2021 00:08:01

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 10 Jun 2021 09:14:49
Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered '20 Jan 2021 15:07'	System	21 Jan 2021 00:08:01

US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:14:49
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:04:14
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered 'Yes (Y)'	Son Do (b) (4)	21 Jan 2021 16:59:36

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US3642086
Folder: Participant Decision Visit / OL-D1 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:14:49
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered '1'	System	21 Jan 2021 16:59:36

FDA-CBER-2022-1614-2895593

US3642086
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:15
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	26 Mar 2021 21:17:34
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:08:31
Signature has been broken.	Megan Loughran (b) (4) (b) (4)	22 Mar 2021 23:05:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	22 Mar 2021 23:05:52
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered 'No (N)'	Lindsey Woronicz (b) (4)	29 Jan 2021 02:06:27

US3642086
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:15
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	26 Mar 2021 21:17:34
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:08:31
Signature has been broken.	Megan Loughran (b) (4) (b) (4)	22 Mar 2021 23:05:52
User entered '27 Jan 2021' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	22 Mar 2021 23:05:52
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered empty.	Lindsey Woronicz (b) (4)	29 Jan 2021 02:06:27

US3642086
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:15
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	26 Mar 2021 21:17:34
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:08:31
Signature has been broken.	Megan Loughran (b) (4) (b) (4)	22 Mar 2021 23:05:52
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	22 Mar 2021 23:05:52
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered empty.	Lindsey Woronicz (b) (4)	29 Jan 2021 02:06:27

US3642086
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:15
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	26 Mar 2021 21:17:34
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:08:31
Signature has been broken.	Megan Loughran (b) (4) (b) (4)	22 Mar 2021 23:05:52
User entered 'unable to reach pt after multiple attempts on 1/27/21, 1/28/21, 1/28/21, email. sent.' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	22 Mar 2021 23:05:52
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered empty.	Lindsey Woronicz (b) (4)	29 Jan 2021 02:06:27

US3642086
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:14:49
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:15
DataPoint Verified.		23 Mar 2021 18:08:33
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered 'Yes (Y)'	Nancy Tang (b) (4)	03 Feb 2021 20:47:38

FDA-CBER-2022-1614-2895598

US3642086
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:14:49
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:15
User entered '1'	System	03 Feb 2021 20:47:38

US3642086
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:14:49
OLD29 Placebo Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:15
User entered '1'	System	03 Feb 2021 20:47:38
DataPoint set to visible.	System	03 Feb 2021 20:47:38

US3642086
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:08:40
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered 'Yes (Y)'	Son Do (b) (4)	25 Feb 2021 16:51:55

FDA-CBER-2022-1614-2895601

US3642086
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:08:40
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered '24 Feb 2021'	Son Do (b) (4)	25 Feb 2021 16:51:55

FDA-CBER-2022-1614-2895602

US3642086
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:08:40
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered 'Clinic (Clinic)'	Son Do (b) (4)	25 Feb 2021 16:51:55

US3642086
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered 'OLD29'	System	25 Feb 2021 16:51:55

FDA-CBER-2022-1614-2895604

US3642086
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User accepted default value 'Pre-Dose (PREDOSE)'	Son Do (b) (4)	25 Feb 2021 16:52:36

FDA-CBER-2022-1614-2895605

US3642086
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:09:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered 'Yes (Y)'	Son Do (b) (4)	25 Feb 2021 16:52:36

FDA-CBER-2022-1614-2895606

US3642086
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:09:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered '24 Feb 2021'	Son Do (b) (4)	25 Feb 2021 16:52:36

FDA-CBER-2022-1614-2895607

US3642086
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:09:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered '13:16'	Son Do (b) (4)	25 Feb 2021 16:52:36

US3642086
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered '24 Feb 2021 13:16'	System	25 Feb 2021 16:52:36

FDA-CBER-2022-1614-2895609

US3642086
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:09:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered '98.7' F	Son Do (b) (4)	25 Feb 2021 16:52:36

US3642086
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:09:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered 'Oral (Oral)'	Son Do (b) (4)	25 Feb 2021 16:52:36

FDA-CBER-2022-1614-2895611

US3642086
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:09:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered empty.	Son Do (b) (4)	25 Feb 2021 16:52:36

US3642086
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:09:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered '70'	Son Do (b) (4)	25 Feb 2021 16:52:36

FDA-CBER-2022-1614-2895613

US3642086
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered 'bpm'	System	25 Feb 2021 16:52:36

FDA-CBER-2022-1614-2895614

US3642086
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:09:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered '16'	Son Do (b) (4)	25 Feb 2021 16:52:36

FDA-CBER-2022-1614-2895615

US3642086
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered 'breaths/min'	System	25 Feb 2021 16:52:36

US3642086
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:09:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered '116'	Son Do (b) (4)	25 Feb 2021 16:52:36

US3642086
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered 'mmHg'	System	25 Feb 2021 16:52:36

FDA-CBER-2022-1614-2895618

US3642086
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:09:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered '72'	Son Do (b) (4)	25 Feb 2021 16:52:36

US3642086
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:14:49
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered 'mmHg'	System	25 Feb 2021 16:52:36

US3642086
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User accepted default value 'Post-Dose (POSTDOSE)'	Son Do (b) (4)	25 Feb 2021 16:52:36

FDA-CBER-2022-1614-2895621

US3642086
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:09:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered 'Yes (Y)'	Son Do (b) (4)	25 Feb 2021 16:52:36

FDA-CBER-2022-1614-2895622

US3642086
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:09:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered '24 Feb 2021'	Son Do (b) (4)	25 Feb 2021 16:52:36

US3642086
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:09:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered '14:50'	Son Do (b) (4)	25 Feb 2021 16:52:36

FDA-CBER-2022-1614-2895624

US3642086
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered '24 Feb 2021 14:50'	System	25 Feb 2021 16:52:36

FDA-CBER-2022-1614-2895625

US3642086
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:09:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered '98.4' F	Son Do (b) (4)	25 Feb 2021 16:52:36

US3642086
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:09:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered 'Oral (Oral)'	Son Do (b) (4)	25 Feb 2021 16:52:36

FDA-CBER-2022-1614-2895627

US3642086
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:09:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered empty.	Son Do (b) (4)	25 Feb 2021 16:52:36

FDA-CBER-2022-1614-2895628

US3642086
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:09:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered '70'	Son Do (b) (4)	25 Feb 2021 16:52:36

US3642086
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered 'bpm'	System	25 Feb 2021 16:52:36

FDA-CBER-2022-1614-2895630

US3642086
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:09:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered '16'	Son Do (b) (4)	25 Feb 2021 16:52:36

FDA-CBER-2022-1614-2895631

US3642086
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered 'breaths/min'	System	25 Feb 2021 16:52:36

US3642086
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:09:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered '105'	Son Do (b) (4)	25 Feb 2021 16:52:36

FDA-CBER-2022-1614-2895633

US3642086
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered 'mmHg'	System	25 Feb 2021 16:52:36

US3642086
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:09:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered '75'	Son Do (b) (4)	25 Feb 2021 16:52:36

FDA-CBER-2022-1614-2895635

US3642086
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:14:49
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered 'mmHg'	System	25 Feb 2021 16:52:36

US3642086
Folder: OL-D29 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:14:49
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:08:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered 'No (N)'	Son Do (b) (4)	25 Feb 2021 16:52:42

FDA-CBER-2022-1614-2895637

US3642086
Folder: OL-D29 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:14:49
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:08:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered empty.	Son Do (b) (4)	25 Feb 2021 16:52:42

FDA-CBER-2022-1614-2895638

US3642086
Folder: OL-D29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:09:41
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered 'Yes (Y)'	Son Do (b) (4)	25 Feb 2021 16:52:55

FDA-CBER-2022-1614-2895639

US3642086
Folder: OL-D29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:09:41
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered empty.	Son Do (b) (4)	25 Feb 2021 16:52:55

US3642086
Folder: OL-D29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:09:41
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered empty.	Son Do (b) (4)	25 Feb 2021 16:52:55

US3642086
Folder: OL-D29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered 'mRNA-1273'	System	25 Feb 2021 16:52:55
DataPoint set to visible.	System	03 Feb 2021 20:47:38

US3642086
Folder: OL-D29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:09:41
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered '24 Feb 2021'	Son Do (b) (4)	25 Feb 2021 16:52:55

FDA-CBER-2022-1614-2895643

US3642086
Folder: OL-D29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:09:41
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered '14:12'	Son Do (b) (4)	25 Feb 2021 16:52:55

FDA-CBER-2022-1614-2895644

US3642086
Folder: OL-D29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered '24 Feb 2021 14:12'	System	25 Feb 2021 16:52:55

FDA-CBER-2022-1614-2895645

US3642086
Folder: OL-D29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:09:41
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:41:13
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 10:07:32
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered with 'patient requested injection to be the right arm' (Site from System).	Son Do (b) (4)	25 Feb 2021 16:53:46
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	25 Feb 2021 16:52:55
User entered 'Right Arm (RIGHT ARM)'	Son Do (b) (4)	25 Feb 2021 16:52:55

FDA-CBER-2022-1614-2895646

US3642086
Folder: OL-D29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:09:41
User entered 'ONCE'	System	25 Feb 2021 16:52:55

US3642086
Folder: OL-D29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:14:49
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered 'INTRAMUSCULAR'	System	25 Feb 2021 16:52:55

US3642086
Folder: OL-D29 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:14:49
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
DataPoint Verified.		23 Mar 2021 18:09:44
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered 'Yes (Y)'	Son Do (b) (4)	25 Feb 2021 16:53:52

FDA-CBER-2022-1614-2895649

US3642086
Folder: OL-D29 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:14:49
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:15
User entered '1'	System	25 Feb 2021 16:53:52

FDA-CBER-2022-1614-2895650

US3642086
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:08:22
DataPoint Verified.		23 Mar 2021 18:12:34
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered 'Yes (Y)'	Jennifer Morales (b) (4) (b) (4)	04 Mar 2021 19:23:27

FDA-CBER-2022-1614-2895651

US3642086
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:08:22
DataPoint Verified.		23 Mar 2021 18:12:34
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered '04 Mar 2021'	Jennifer Morales (b) (4) (b) (4)	04 Mar 2021 19:23:27

US3642086
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:08:22
DataPoint Verified.		23 Mar 2021 18:12:34
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered 'Contact Made (CONTACT MADE)'	Jennifer Morales (b) (4) (b) (4)	04 Mar 2021 19:23:27

US3642086
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:14:49
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:08:22
DataPoint Verified.		23 Mar 2021 18:12:34
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered empty.	Jennifer Morales (b) (4) (b) (4)	04 Mar 2021 19:23:27

FDA-CBER-2022-1614-2895654

US3642086
Folder: Safety Call OL-D36 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:14:49
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:08:22
DataPoint Verified.		23 Mar 2021 18:12:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:41:13
User entered 'Yes (Y)'	Jennifer Morales (b) (4) (b) (4)	04 Mar 2021 19:23:33

FDA-CBER-2022-1614-2895655

US3642086
Folder: Safety Call OL-D36 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:14:49
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:08:22
User entered '1'	System	04 Mar 2021 19:23:33

FDA-CBER-2022-1614-2895656

US3642086
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:20
DataPoint Verified.		20 Apr 2021 17:00:18
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:28:27
User entered 'Yes (Y)'	Son Do (b) (4)	30 Mar 2021 15:13:22

FDA-CBER-2022-1614-2895657

US3642086
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:20
DataPoint Verified.		20 Apr 2021 17:00:18
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:28:27
User entered '25 Mar 2021'	Son Do (b) (4)	30 Mar 2021 15:13:22

FDA-CBER-2022-1614-2895658

US3642086
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:20
DataPoint Verified.		20 Apr 2021 17:00:18
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:28:27
User entered 'Clinic (Clinic)'	Son Do (b) (4)	30 Mar 2021 15:13:22

FDA-CBER-2022-1614-2895659

US3642086
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:14:49
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:20
User entered 'OLD57'	System	30 Mar 2021 15:13:22

FDA-CBER-2022-1614-2895660

US3642086
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:20
DataPoint Verified.		20 Apr 2021 17:00:24
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:28:27
User entered 'No (N)'	Son Do (b) (4)	30 Mar 2021 15:13:30

FDA-CBER-2022-1614-2895661

US3642086
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:20
DataPoint Verified.		20 Apr 2021 17:00:24
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:28:27
User entered empty.	Son Do (b) (4)	30 Mar 2021 15:13:30

FDA-CBER-2022-1614-2895662

US3642086
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:20
DataPoint Verified.		20 Apr 2021 17:00:24
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:28:27
User entered empty.	Son Do (b) (4)	30 Mar 2021 15:13:30

FDA-CBER-2022-1614-2895663

US3642086
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:20
User entered empty.	System	30 Mar 2021 15:13:30

FDA-CBER-2022-1614-2895664

US3642086
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:20
DataPoint Verified.		20 Apr 2021 17:00:24
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:28:27
User entered empty.	Son Do (b) (4)	30 Mar 2021 15:13:30

FDA-CBER-2022-1614-2895665

US3642086
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:20
DataPoint Verified.		20 Apr 2021 17:00:24
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:28:27
User entered empty.	Son Do (b) (4)	30 Mar 2021 15:13:30

FDA-CBER-2022-1614-2895666

US3642086
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:20
DataPoint Verified.		20 Apr 2021 17:00:24
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:28:27
User entered empty.	Son Do (b) (4)	30 Mar 2021 15:13:30

US3642086
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:20
DataPoint Verified.		20 Apr 2021 17:00:24
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:28:27
User entered empty.	Son Do (b) (4)	30 Mar 2021 15:13:30

FDA-CBER-2022-1614-2895668

US3642086
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:20
User entered empty.	System	30 Mar 2021 15:13:30

US3642086
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:20
DataPoint Verified.		20 Apr 2021 17:00:24
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:28:27
User entered empty.	Son Do (b) (4)	30 Mar 2021 15:13:30

FDA-CBER-2022-1614-2895670

US3642086
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:20
User entered empty.	System	30 Mar 2021 15:13:30

US3642086
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:20
DataPoint Verified.		20 Apr 2021 17:00:24
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:28:27
User entered empty.	Son Do (b) (4)	30 Mar 2021 15:13:30

FDA-CBER-2022-1614-2895672

US3642086
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:20
User entered empty.	System	30 Mar 2021 15:13:30

FDA-CBER-2022-1614-2895673

US3642086
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:20
DataPoint Verified.		20 Apr 2021 17:00:24
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:28:27
User entered empty.	Son Do (b) (4)	30 Mar 2021 15:13:30

FDA-CBER-2022-1614-2895674

US3642086
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:20
User entered empty.	System	30 Mar 2021 15:13:30

FDA-CBER-2022-1614-2895675

US3642086
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:20

FDA-CBER-2022-1614-2895676

US3642086
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:14:49
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:20

FDA-CBER-2022-1614-2895677

US3642086
Folder: OL-D57 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:14:49
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:20
DataPoint Verified.		20 Apr 2021 17:00:39
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:28:27
User entered 'No (N)'	Son Do (b) (4)	30 Mar 2021 15:13:41

US3642086
Folder: OL-D57 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:14:49
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:20
DataPoint Verified.		20 Apr 2021 17:00:39
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:28:27
User entered empty.	Son Do (b) (4)	30 Mar 2021 15:13:41

FDA-CBER-2022-1614-2895679

US3642086
Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:14:49
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:20
DataPoint Verified.		20 Apr 2021 17:00:43
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:28:27
User entered 'Yes (Y)'	Son Do (b) (4)	30 Mar 2021 15:13:52

US3642086
Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:14:49
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:20
DataPoint Verified.		20 Apr 2021 17:00:43
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:28:27
User entered '25 Mar 2021'	Son Do (b) (4)	30 Mar 2021 15:13:52

FDA-CBER-2022-1614-2895681

US3642086
Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:14:49
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:20
DataPoint Verified.		20 Apr 2021 17:00:43
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:28:27
User entered '15:21'	Son Do (b) (4)	30 Mar 2021 15:13:52

FDA-CBER-2022-1614-2895682

US3642086
Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:14:49
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:20
User entered '25 Mar 2021 15:21'	System	30 Mar 2021 15:13:52

US3642086
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 10 Jun 2021 09:14:49
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:42:55
DataPoint Verified.		23 Mar 2021 18:36:23
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Un-verified.	Nancy Tang (b) (4)	24 Dec 2020 22:37:00
User entered 'Yes (Y)' reason for change: New Information	Nancy Tang (b) (4)	24 Dec 2020 22:37:00
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 19:44:55
User entered 'No (N)'	Son Do (b) (4)	05 Oct 2020 18:29:48

US3642086
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:14:49
AEID

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:41:06
Reviewed for Safety.		29 Dec 2020 19:54:58
User entered 'USA-US109-2020-mRNA-1273-P301000010'	System	29 Dec 2020 19:54:54
User entered 'New'	(b) (4), (b) (6)	29 Dec 2020 19:54:54

US3642086
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:14:49
Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:41:06
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Dec 2020 22:40:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Dec 2020 22:40:29
Data point term sent to Coder	System	24 Dec 2020 22:40:00
User entered 'Covid19'	Nancy Tang (b) (4)	24 Dec 2020 22:39:53

US3642086
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:14:49
Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:41:06
User entered 'Yes (Y)'	Nancy Tang (b) (4)	24 Dec 2020 22:39:53

US3642086
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:14:49
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:41:06
User entered 'No (N)'	Nancy Tang (b) (4)	24 Dec 2020 22:39:53

US3642086
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:14:49
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:41:06
User entered 'Yes (Y)'	Nancy Tang (b) (4)	24 Dec 2020 22:39:53

US3642086
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:14:49
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:41:06
User entered '18 Dec 2020'	Nancy Tang (b) (4)	24 Dec 2020 22:39:53

FDA-CBER-2022-1614-2895690

US3642086
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:14:49
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:41:06
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:39:53

US3642086
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:14:49
AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Dec 2020 22:39:53

US3642086
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:14:49
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:41:06
User entered 'No (N)' reason for change: New Information	Nancy Tang (b) (4)	13 Jan 2021 17:09:29
User entered 'Yes (Y)'	Nancy Tang (b) (4)	24 Dec 2020 22:39:53

FDA-CBER-2022-1614-2895693

US3642086
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:14:49
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:41:06
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		14 Jan 2021 00:23:06
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Subject have returned to baseline. All symptoms resolved and saliva pcr negative.' (Site from Safety).	Nancy Tang (b) (4)	13 Jan 2021 17:09:59
User entered '11 Jan 2021' reason for change: New Information	Nancy Tang (b) (4)	13 Jan 2021 17:09:29
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 14:30:33
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:39:53

US3642086
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:14:49
End time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:41:06
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:39:53

US3642086
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:14:49
AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Dec 2020 22:39:53

US3642086
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:14:49
Severity

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:41:06
User entered 'Grade 3/Severe (Grade 3/Severe)'	Nancy Tang (b) (4)	24 Dec 2020 22:39:53

FDA-CBER-2022-1614-2895697

US3642086
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:14:49
Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:41:06
User entered 'No (N)'	Nancy Tang (b) (4)	24 Dec 2020 22:39:53

US3642086
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:14:49
Death

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:41:06
User entered '0'	Nancy Tang (b) (4)	24 Dec 2020 22:39:53

US3642086
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:14:49
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:41:06
User entered '0'	Nancy Tang (b) (4)	24 Dec 2020 22:39:53

US3642086
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:14:49
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:41:06
User entered '0'	Nancy Tang (b) (4)	24 Dec 2020 22:39:53

US3642086
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:14:49
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:41:06
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:39:53

US3642086
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:14:49
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:41:06
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:39:53

US3642086
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:14:49
Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:41:06
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:39:53

US3642086
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:14:49
Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:41:06
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:39:53

US3642086
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:14:49
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:41:06
User entered '0'	Nancy Tang (b) (4)	24 Dec 2020 22:39:53

US3642086
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:14:49
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:41:06
User entered '0'	Nancy Tang (b) (4)	24 Dec 2020 22:39:53

US3642086
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:14:49
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:41:06
User entered '0'	Nancy Tang (b) (4)	24 Dec 2020 22:39:53

US3642086
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:14:49
Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:41:06
User entered 'Not Related (NOT RELATED)'	Nancy Tang (b) (4)	24 Dec 2020 22:39:53

US3642086
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:14:49
Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:41:06
User entered 'Not Related (NOT RELATED)'	Nancy Tang (b) (4)	24 Dec 2020 22:39:53

US3642086
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:14:49
Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 21:41:06
User entered 'Not Applicable (NOT APPLICABLE)'	Nancy Tang (b) (4)	24 Dec 2020 22:39:53

US3642086
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:14:49
None

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:41:06
User entered '0'	Nancy Tang (b) (4)	24 Dec 2020 22:39:53

US3642086
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:14:49
Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:41:06
User entered '1'	Nancy Tang (b) (4)	24 Dec 2020 22:39:53

FDA-CBER-2022-1614-2895713

US3642086
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:14:49
Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:41:06
User entered '0'	Nancy Tang (b) (4)	24 Dec 2020 22:39:53

FDA-CBER-2022-1614-2895714

US3642086
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:14:49
Outcome

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:41:06
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).		14 Jan 2021 00:23:10
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'Subject returned to baseline and all symptoms resolved. Saliva pcr negative.' (Site from Safety).	Nancy Tang (b) (4)	13 Jan 2021 17:10:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Nancy Tang (b) (4)	13 Jan 2021 17:09:29
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 14:32:20
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Nancy Tang (b) (4)	24 Dec 2020 22:39:53

FDA-CBER-2022-1614-2895715

US3642086
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:14:49
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:41:06
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:39:53

US3642086
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:14:49
Narrative

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 21:41:06
User entered 'Subject reports that he experienced Covid19 symptoms and was tested and treated in the Emergency department. He then came in for an illness visit. Covid19 currently being treated with prescribed medications. Subject will continue to remain on the study.'	Nancy Tang (b) (4)	24 Dec 2020 22:39:53

US3642086
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:14:49
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	24 Dec 2020 22:39:53

US3642086
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:14:49
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	24 Dec 2020 22:39:53

US3642086
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:14:49
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:59:31

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US3642086
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:14:49
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:59:31
DataPoint Verified.		23 Mar 2021 18:13:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	19 Mar 2021 23:56:11
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Diabetes mellitus inadequate control, LLT: Type II diabetes mellitus inadequate control - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 19:15:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 19:15:34
Data point term sent to Coder	System	15 Mar 2021 19:14:59
User entered 'UNCONTROLLED TYPE 2 DIABETES'	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:00

US3642086
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:14:49
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:59:31
DataPoint Verified.		23 Mar 2021 18:13:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	19 Mar 2021 23:56:11
User entered 'Yes (Y)'	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:00

US3642086
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:14:49
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:59:31
DataPoint Verified.		23 Mar 2021 18:13:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	19 Mar 2021 23:56:11
User entered 'No (N)'	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:00

US3642086
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:14:49
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:59:31
DataPoint Verified.		23 Mar 2021 18:13:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	19 Mar 2021 23:56:11
User entered 'No (N)'	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:00

US3642086
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:14:49
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:59:31
DataPoint Verified.		23 Mar 2021 18:13:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	19 Mar 2021 23:56:11
User entered '03 Mar 2021'	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:00

US3642086
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:14:49
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:59:31
DataPoint Verified.		23 Mar 2021 18:13:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	19 Mar 2021 23:56:11
User entered empty.	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:00

US3642086
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:14:49
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:59:31
User entered empty.	System	15 Mar 2021 19:14:00

US3642086
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:14:49
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:59:31
DataPoint Verified.		29 Apr 2021 19:37:32
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	28 Apr 2021 23:40:00
DataPoint Un-verified.	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:36:55
Signature has been broken.	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:36:55
User entered 'No (N)' reason for change: Data Entry Error	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:36:55
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:13:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	19 Mar 2021 23:56:11
User entered 'Yes (Y)'	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:00

US3642086
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:14:49
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:59:31
DataPoint Verified.		29 Apr 2021 19:37:32
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	28 Apr 2021 23:40:00
DataPoint Un-verified.	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:36:55
Signature has been broken.	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:36:55
User entered '28 Apr 2021' reason for change: Data Entry Error	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:36:55
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:13:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	19 Mar 2021 23:56:11
User entered empty.	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:00

US3642086
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:14:49
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:59:31
DataPoint Verified.		23 Mar 2021 18:13:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	19 Mar 2021 23:56:11
User entered empty.	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:00

US3642086
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:14:49
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:59:31
User entered empty.	System	15 Mar 2021 19:14:00

US3642086
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:14:49
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:59:31
DataPoint Verified.		23 Mar 2021 18:13:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	19 Mar 2021 23:56:11
User entered 'Grade 1/Mild (Grade 1/Mild)'	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:00

US3642086
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:14:49
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:59:31
DataPoint Verified.		23 Mar 2021 18:13:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	19 Mar 2021 23:56:11
User entered 'No (N)'	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:00

US3642086
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:14:49
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:59:31
DataPoint Verified.		23 Mar 2021 18:13:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	19 Mar 2021 23:56:11
User entered '0'	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:00

US3642086
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:14:49
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:59:31
DataPoint Verified.		23 Mar 2021 18:13:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	19 Mar 2021 23:56:11
User entered '0'	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:00

US3642086
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:14:49
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:59:31
DataPoint Verified.		23 Mar 2021 18:13:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	19 Mar 2021 23:56:11
User entered '0'	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:00

US3642086
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:14:49
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:59:31
DataPoint Verified.		23 Mar 2021 18:13:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	19 Mar 2021 23:56:11
User entered empty.	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:00

US3642086
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:14:49
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:59:31
DataPoint Verified.		23 Mar 2021 18:13:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	19 Mar 2021 23:56:11
User entered empty.	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:00

US3642086
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:14:49
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:59:31
DataPoint Verified.		23 Mar 2021 18:13:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	19 Mar 2021 23:56:11
User entered empty.	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:00

US3642086
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:14:49
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:59:31
DataPoint Verified.		23 Mar 2021 18:13:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	19 Mar 2021 23:56:11
User entered empty.	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:00

US3642086
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:14:49
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:59:31
DataPoint Verified.		23 Mar 2021 18:13:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	19 Mar 2021 23:56:11
User entered '0'	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:00

US3642086
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:14:49
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:59:31
DataPoint Verified.		23 Mar 2021 18:13:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	19 Mar 2021 23:56:11
User entered '0'	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:00

US3642086
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:14:49
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:59:31
DataPoint Verified.		23 Mar 2021 18:13:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	19 Mar 2021 23:56:11
User entered '0'	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:00

US3642086
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:14:49
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:59:31
DataPoint Verified.		23 Mar 2021 18:13:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	19 Mar 2021 23:56:11
User entered 'Not Related (NOT RELATED)'	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:00

US3642086
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:14:49
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:59:31
DataPoint Verified.		23 Mar 2021 18:13:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	19 Mar 2021 23:56:11
User entered 'Not Related (NOT RELATED)'	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:00

US3642086
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:14:49
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:59:31
DataPoint Verified.		23 Mar 2021 18:13:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	19 Mar 2021 23:56:11
User entered 'Not Applicable (NOT APPLICABLE)'	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:00

US3642086
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:14:49
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:59:31
DataPoint Verified.		23 Mar 2021 18:13:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	19 Mar 2021 23:56:11
User entered '0'	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:00

US3642086
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:14:49
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:59:31
DataPoint Verified.		23 Mar 2021 18:13:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	19 Mar 2021 23:56:11
User entered '1'	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:00

US3642086
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:14:49
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:59:31
DataPoint Verified.		23 Mar 2021 18:13:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	19 Mar 2021 23:56:11
User entered '0'	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:00

US3642086
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:14:49
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:59:31
DataPoint Verified.		29 Apr 2021 19:37:32
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	28 Apr 2021 23:40:00
DataPoint Un-verified.	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:36:55
Signature has been broken.	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:36:55
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:36:55
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:13:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	19 Mar 2021 23:56:11
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:00

US3642086
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:14:49
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:59:31
DataPoint Verified.		23 Mar 2021 18:13:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	19 Mar 2021 23:56:11
User entered empty.	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:00

US3642086
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:14:49
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:59:31
DataPoint Verified.		29 Apr 2021 19:37:32
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	28 Apr 2021 23:40:00
DataPoint Un-verified.	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:37:49
Signature has been broken.	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:37:49
User entered 'PATIENT REPORTS THAT HIS PCP ADDED IN A NEW MEDICATION FOR BETTER MANAGEMENT OF HIS TYPE 2 DIABETES. PATIENT CURRENTLY TAKES METFORMIN AND JARDIANCE DAILY. TRULICITY SQ WEEKLY ADDED TO REGIMEN. PATIENT UNABLE TO PROVIDE SPECIFIC LAB VALUES DISCUSSED WITH PROVIDER (HGA1C, GLUCOSE ETC). UNABLE TO ACCESS MEDICAL RECORDS THROUGH CARE EVERYWHERE AS THE PATIENT GETS CARE THROUGH THE VA. MEDICAL RECORDS WILL BE REQUESTED BY STUDY TEAM. CONDITION IS ONGOING AND PATIENT WILL REMAIN ON STUDY. UPDATE: PATIENT REPORTS TODAY THAT HIS TYPE 2 DIABETES IS WELL CONTROLLED AND THAT HIS BLOOD SUGARS ARE WNL AT HOME.' reason for change: Data Entry Error	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:37:49
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:13:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	19 Mar 2021 23:56:11

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US3642086
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:14:49
Narrative

Audit	User	Time (GMT)
User entered 'PATIENT REPORTS THAT HIS PCP ADDED IN A NEW MEDICATION FOR BETTER MANAGEMENT OF HIS TYPE 2 DIABETES. PATIENT CURRENTLY TAKES METFORMIN AND JARDIANCE DAILY. TRULICITY SQ WEEKLY ADDED TO REGIMEN. PATIENT UNABLE TO PROVIDE SPECIFIC LAB VALUES DISCUSSED WITH PROVIDER (HGA1C, GLUCOSE ETC). UNABLE TO ACCESS MEDICAL RECORDS THROUGH CARE EVERYWHERE AS THE PATIENT GETS CARE THROUGH THE VA. MEDICAL RECORDS WILL BE REQUESTED BY STUDY TEAM. CONDITION IS ONGOING AND PATIENT WILL REMAIN ON STUDY.'	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:00

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US3642086
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:14:49
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:59:31
User entered '0'	System	15 Mar 2021 19:14:00

US3642086
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:14:49
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:59:31
User entered '1'	System	15 Mar 2021 19:14:00

US3642086
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:14:49
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:59:31

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US3642086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:14:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:42:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
User closed query 'Per source subject reported taking Lipitor. Please add record. ' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 22:13:58
Query 'Per source subject reported taking Lipitor. Please add record. ' answered with 'added' (Site from CRA).	Megan Loughran (b) (4)	24 Nov 2020 18:35:32
User opened query 'Per source subject reported taking Lipitor. Please add record. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 20:13:27
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:01:06
User entered 'Yes (Y)'	Son Do (b) (4)	05 Oct 2020 16:37:35

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:14:49
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:21:19
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:40:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:40:37
Data point term sent to Coder	System	05 Oct 2020 16:39:08
User entered 'metformin'	Son Do (b) (4)	05 Oct 2020 16:38:12

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US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:14:49
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:21:19
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'No (N)'	Son Do (b) (4)	05 Oct 2020 16:38:12

FDA-CBER-2022-1614-2895759

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:14:49
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:21:19
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'diabetes type 2'	Son Do (b) (4)	05 Oct 2020 16:38:12

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:14:49
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:21:19
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '1000'	Son Do (b) (4)	05 Oct 2020 16:38:12

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US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:14:49
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:21:19
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'mg (mg)'	Son Do (b) (4)	05 Oct 2020 16:38:12

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US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:14:49
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:21:19
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Son Do (b) (4)	05 Oct 2020 16:38:12

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:14:49
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:21:19
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User closed query 'Per source scr/visit 1 frequency is documented as 'QD', visit 2 is documented as 'twice daily'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	18 Dec 2020 19:37:18
Query 'Per source scr/visit 1 frequency is documented as 'QD', visit 2 is documented as 'twice daily'. Please reconcile. ' answered with 'data are correct - twice daily. source has been revised. ' (Site from CRA).	Megan Loughran (b) (4) (b) (4)	24 Nov 2020 18:23:53
User opened query 'Per source scr/visit 1 frequency is documented as 'QD', visit 2 is documented as 'twice daily'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 20:07:12
User entered 'twice daily (BID)'	Son Do (b) (4)	05 Oct 2020 16:38:12

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:14:49
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:21:19
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Son Do (b) (4)	05 Oct 2020 16:38:12

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US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:14:49
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:21:19
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Oral (ORAL)'	Son Do (b) (4)	05 Oct 2020 16:38:12

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:14:49
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:21:19
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Son Do (b) (4)	05 Oct 2020 16:38:12

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US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:14:49
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:21:19
User closed query 'Per source screening/D1 visit start date is documented as 'un-unk-2015'. Please reconcile. ' (Site from CRA).		23 Feb 2021 03:41:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
Query 'Per source screening/D1 visit start date is documented as 'un-unk-2015'. Please reconcile. ' answered with 'this information was provided by participant at visit 2, as documented in source. visit 1 source has been updated to reflect the additional information.' (Site from CRA).	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 19:40:19
User opened query 'Per source screening/D1 visit start date is documented as 'un-unk-2015'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	18 Dec 2020 19:38:11
User closed query 'Per source scr/visit 1 start date is documented as 'un-unk-2015', visit 2 as 'un-Feb-2017'. Please reconcile.' (Site from CRA).		18 Dec 2020 19:38:11
Query 'Per source scr/visit 1 start date is documented as 'un-unk-2015', visit 2 as 'un-Feb-2017'. Please reconcile.' answered with '2015 is correct; revised. ' (Site from CRA).	Megan Loughran (b) (4) (b) (4)	24 Nov 2020 18:24:12
User entered 'UN Feb 2015' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	24 Nov 2020 18:23:58
User opened query 'Per source scr/visit 1 start date is documented as 'un-unk-2015', visit 2 as 'un-Feb-2017'. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 20:07:55
User entered 'UN Feb 2017'	Son Do (b) (4)	05 Oct 2020 16:38:12

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US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:14:49
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:21:19
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '0'	Son Do (b) (4)	05 Oct 2020 16:38:12

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:14:49
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:37:49
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	28 Apr 2021 23:40:00
DataPoint Un-verified.	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:21:45
Signature has been broken.	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:21:45
User entered 'No (N)' reason for change: Data Entry Error	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:21:45
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:21:19
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Yes (Y)'	Son Do (b) (4)	05 Oct 2020 16:38:12

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US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:14:49
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:37:49
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	28 Apr 2021 23:40:00
DataPoint Un-verified.	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:21:45
Signature has been broken.	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:21:45
User entered '06 Apr 2021' reason for change: Data Entry Error	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:21:45
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:21:19
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Son Do (b) (4)	05 Oct 2020 16:38:12

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:14:49
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:21:19
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
User entered 'No (N)'	Son Do (b) (4)	05 Oct 2020 16:38:12

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US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:14:49
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	05 Oct 2020 16:38:12

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:14:49
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 16:38:12

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:14:49
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 16:38:12

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:14:49
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:21:42
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
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) (b) (4)	24 Nov 2020 18:27:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 18:27:05
Data point term sent to Coder	System	24 Nov 2020 18:26:28
Coding entries removed.	Megan Loughran (b) (4) (b) (4)	24 Nov 2020 18:26:03
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) (b) (4)	05 Oct 2020 16:40:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:40:23
Data point term sent to Coder	System	05 Oct 2020 16:39:09
User entered 'omeprazole'	Son Do (b) (4)	05 Oct 2020 16:38:43

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US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:14:49
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:21:42
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'No (N)'	Son Do (b) (4)	05 Oct 2020 16:38:43

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:14:49
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:21:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
User closed query 'Please spell-out indication. ' (Site from CRA).	(b) (4), (b) (6)	18 Dec 2020 19:38:30
Query 'Please spell-out indication. ' answered with 'revised' (Site from CRA).	Megan Loughran (b) (4)	24 Nov 2020 18:26:17
User entered 'Gastroesophageal reflux disease' reason for change: Data Entry Error	Megan Loughran (b) (4)	24 Nov 2020 18:26:03
User opened query 'Please spell-out indication. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 20:03:33
User entered 'gerd'	Son Do (b) (4)	05 Oct 2020 16:38:43

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:14:49
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:21:42
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '20'	Son Do (b) (4)	05 Oct 2020 16:38:43

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:14:49
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:21:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
User entered 'mg (mg)'	Son Do (b) (4)	05 Oct 2020 16:38:43

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:14:49
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:21:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Son Do (b) (4)	05 Oct 2020 16:38:43

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US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:14:49
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:21:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
User closed query 'Per source scr/visit 1 frequency is documented as 'PRN', visit 2 is documented as 'QD'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	18 Dec 2020 19:39:05
Query 'Per source scr/visit 1 frequency is documented as 'PRN', visit 2 is documented as 'QD'. Please reconcile. ' answered with 'reconciled' (Site from CRA).	Megan Loughran (b) (4)	24 Nov 2020 18:26:30
User entered 'as needed (PRN)' reason for change: Data Entry Error	Megan Loughran (b) (4)	24 Nov 2020 18:26:23
User opened query 'Per source scr/visit 1 frequency is documented as 'PRN', visit 2 is documented as 'QD'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 20:04:46
User entered 'once daily (QD)'	Son Do (b) (4)	05 Oct 2020 16:38:43

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:14:49
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:21:42
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Son Do (b) (4)	05 Oct 2020 16:38:43

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:14:49
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:21:42
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Oral (ORAL)'	Son Do (b) (4)	05 Oct 2020 16:38:43

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:14:49
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:21:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Son Do (b) (4)	05 Oct 2020 16:38:43

FDA-CBER-2022-1614-2895785

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:14:49
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:21:42
User closed query 'Per source screening/D1 visit start date is documented as 'un-unk-2014'. Please reconcile. ' (Site from CRA).		23 Feb 2021 03:42:14
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
Query 'Per source screening/D1 visit start date is documented as 'un-unk-2014'. Please reconcile. ' answered with 'this information was provided by participant at visit 2, as documented in source. visit 1 source has been updated to reflect the additional information.' (Site from CRA).	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 19:40:25
User opened query 'Per source screening/D1 visit start date is documented as 'un-unk-2014'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	18 Dec 2020 19:41:00
User closed query 'Per source scr/visit 1 start date is documented as 'un-unk-2014', visit 2 as 'un-unk-2017'. Please reconcile. ' (Site from CRA).		18 Dec 2020 19:41:00
Query 'Per source scr/visit 1 start date is documented as 'un-unk-2014', visit 2 as 'un-unk-2017'. Please reconcile. ' answered with 'revised' (Site from CRA).	Megan Loughran (b) (4) (b) (4)	24 Nov 2020 18:26:37
User entered 'UN Feb 2014' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	24 Nov 2020 18:26:03
User opened query 'Per source scr/visit 1 start date is documented as 'un-unk-2014', visit 2 as 'un-unk-2017'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 20:06:02
User entered 'UN Feb 2017'	Son Do (b) (4)	05 Oct 2020 16:38:43

FDA-CBER-2022-1614-2895786

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:14:49
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:21:42
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '0'	Son Do (b) (4)	05 Oct 2020 16:38:43

FDA-CBER-2022-1614-2895787

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:14:49
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:21:42
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Yes (Y)'	Son Do (b) (4)	05 Oct 2020 16:38:43

FDA-CBER-2022-1614-2895788

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:14:49
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:21:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Son Do (b) (4)	05 Oct 2020 16:38:43

FDA-CBER-2022-1614-2895789

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:14:49
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:21:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
User entered 'No (N)'	Son Do (b) (4)	05 Oct 2020 16:38:43

FDA-CBER-2022-1614-2895790

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:14:49
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 18:26:23
User entered '1'	System	05 Oct 2020 16:38:43

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:14:49
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 18:26:23
User entered '1'	System	05 Oct 2020 16:38:43

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:14:49
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 18:26:23
User entered '804 (804)'	System	05 Oct 2020 16:38:43

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:14:49
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 19:57:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 19:57:23
Data point term sent to Coder	System	06 Nov 2020 19:56:59
User entered 'tylenol'	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:56:44

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:14:49
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:47
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:56:44

FDA-CBER-2022-1614-2895795

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:14:49
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 04:59:18
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' answered with 'reported in ediary; no additional ae required as this is a solicited event lasting less than 48 hours within 7 days of injection. ' (Site from DM).	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 19:46:03

FDA-CBER-2022-1614-2895796

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:14:49
Indication

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 21:37:24
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:47
User entered 'headache'	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:56:44

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:14:49
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:47
User entered '500'	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:56:44

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:14:49
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:47
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:56:44

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:14:49
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:47
User entered empty.	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:56:44

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:14:49
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:47
User entered 'twice daily (BID)'	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:56:44

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:14:49
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:47
User entered empty.	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:56:44

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:14:49
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:47
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:56:44

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:14:49
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:47
User entered empty.	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:56:44

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:14:49
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:47
User entered '02 Oct 2020'	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:56:44

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:14:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:47
User entered '0'	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:56:44

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:14:49
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:47
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:56:44

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:14:49
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:47
User entered '02 Oct 2020'	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:56:44

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:14:49
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:47
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:56:44

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:14:49
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:28
User entered '2'	System	06 Nov 2020 19:56:44

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:14:49
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:28
User entered '1'	System	06 Nov 2020 19:56:44

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:14:49
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:28
User entered '804 (804)'	System	06 Nov 2020 19:56:44

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:14:49
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:32
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 18:19:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 18:19:56
Data point term sent to Coder	System	24 Nov 2020 18:19:19
Coding entries removed.	Megan Loughran (b) (4) (b) (4)	24 Nov 2020 18:18:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:44
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 19:59:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 19:59:21
Data point term sent to Coder	System	06 Nov 2020 19:59:02
User entered 'flu vaccine'	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:58:29

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:14:49
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:32
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:44
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:58:29

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:14:49
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:32
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 19:41:16
User closed query 'Per eCRF completion guidelines, if taken as prophylaxis, we recommend reporting as “Prophylaxis for…”.' (Site from CRA).	(b) (4), (b) (6)	18 Dec 2020 19:41:14
Query 'Per eCRF completion guidelines, if taken as prophylaxis, we recommend reporting as “Prophylaxis for…”.' answered with 'revised' (Site from CRA).	Megan Loughran (b) (4) (b) (4)	24 Nov 2020 18:18:37
User entered 'prophylaxis for flu' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	24 Nov 2020 18:18:31
User opened query 'Per eCRF completion guidelines, if taken as prophylaxis, we recommend reporting as “Prophylaxis for…”.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 20:12:10
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:52
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:44
User entered 'vaccine'	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:58:29

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:14:49
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:32
DataPoint Verified.		23 Mar 2021 18:24:05
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Un-verified.	Benjamin Hull (b) (4) (b) (4)	14 Jan 2021 19:06:15
User entered '0.5' reason for change: Data Entry Error	Benjamin Hull (b) (4) (b) (4)	14 Jan 2021 19:06:15
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:44
User entered '1'	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:58:29

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:14:49
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:32
DataPoint Verified.		23 Mar 2021 18:24:08
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Un-verified.	Benjamin Hull (b) (4) (b) (4)	14 Jan 2021 19:06:15
User entered 'mL (mL)' reason for change: Data Entry Error	Benjamin Hull (b) (4) (b) (4)	14 Jan 2021 19:06:15
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:44
User entered 'Other (OTHER)'	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:58:29

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:14:49
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:32
DataPoint Verified.		23 Mar 2021 18:24:10
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Un-verified.	Benjamin Hull (b) (4) (b) (4)	14 Jan 2021 19:06:15
User entered empty; reason for change Data Entry Error	Benjamin Hull (b) (4) (b) (4)	14 Jan 2021 19:06:15
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:44
User entered 'injection'	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:58:29

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:14:49
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:32
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:44
User entered 'once (ONCE)'	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:58:29

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:14:49
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:32
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:44
User entered empty.	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:58:29

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:14:49
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:32
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:44
User entered 'Intramuscular (INTRAMUSCULAR)'	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:58:29

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:14:49
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:32
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:44
User entered empty.	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:58:29

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:14:49
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:32
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:44
User entered '23 Oct 2020'	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:58:29

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:14:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:32
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:44
User entered '0'	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:58:29

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:14:49
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:32
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:44
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:58:29

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:14:49
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:32
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:44
User entered '23 Oct 2020'	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:58:29

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:14:49
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:32
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:44
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:58:29

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:14:49
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:32
User entered empty.	System	06 Nov 2020 19:58:29

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:14:49
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:32
User entered empty.	System	06 Nov 2020 19:58:29

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:14:49
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:32
User entered empty.	System	06 Nov 2020 19:58:29

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:14:49
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening DIABETES TYPE II should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 05:01:41
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening DIABETES TYPE II should be recorded, and update con med indication or provide clarification. ' answered with 'medication added d/t pt/pcp decision. no ae required. ' (Site from DM).	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 19:52:22
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening DIABETES TYPE II should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 21:38:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS, PRODUCT: EMPAGLIFLOZIN, PRODUCTSYNONYM: JARDIANCE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 21:54:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 21:54:50
Data point term sent to Coder	System	17 Nov 2020 21:54:07
Coding entries removed.	Megan Loughran (b) (4) (b) (4)	17 Nov 2020 21:53:47

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:14:49
Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS, PRODUCT: EMPAGLIFLOZIN, PRODUCTSYNONYM: JARDIANCE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:01:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:01:21
Data point term sent to Coder	System	06 Nov 2020 20:00:04
User entered 'jardiance'	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:59:04

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:14:49
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:37
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:59:04

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:14:49
Indication

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:37
User entered 'DIABETES type II' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	17 Nov 2020 21:53:47
User entered 'diabetes'	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:59:04

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:14:49
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:37
User entered '25'	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:59:04

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:14:49
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:37
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:59:04

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:14:49
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:37
User entered empty.	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:59:04

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:14:49
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:37
User entered 'once daily (QD)'	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:59:04

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:14:49
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:37
User entered empty.	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:59:04

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:14:49
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:37
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:59:04

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:14:49
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:37
User entered empty.	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:59:04

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:14:49
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:37
User entered '26 Oct 2020'	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:59:04

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:14:49
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:37
User entered '0'	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:59:04

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:14:49
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:37
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:59:04

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:14:49
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:37
User entered empty.	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:59:04

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:14:49
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:37
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	06 Nov 2020 19:59:04

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:14:49
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 19:59:04

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:14:49
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 19:59:04

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:14:49
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 19:59:04

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:14:49
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 19:44:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 18:36:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 18:36:56
Data point term sent to Coder	System	24 Nov 2020 18:35:37
User entered 'lipitor'	Megan Loughran (b) (4) (b) (4)	24 Nov 2020 18:35:27

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:14:49
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 19:44:25
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	24 Nov 2020 18:35:27

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:14:49
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User closed query 'Per DM CLR: Was this medication added because the patients Med History of HYPERCHOLESTEROLEMIA worsened? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for the addition of the new medication. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 05:02:13
Query 'Per DM CLR: Was this medication added because the patients Med History of HYPERCHOLESTEROLEMIA worsened? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for the addition of the new medication. ' answered with 'patient has ongoing condition of hypercholesterolemia and is not on therapy. decided to start treatment for this ongoing condition. no ae is required. ' (Site from DM).	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 19:49:26
User opened query 'Per DM CLR: Was this medication added because the patients Med History of HYPERCHOLESTEROLEMIA worsened? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for the addition of the new medication. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 12:54:05
DataPoint Verified.		18 Dec 2020 19:44:25
User entered 'hypercholesterolemia'	Megan Loughran (b) (4) (b) (4)	24 Nov 2020 18:35:27

FDA-CBER-2022-1614-2895852

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:14:49
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 19:44:25
User entered 'UN'	Megan Loughran (b) (4) (b) (4)	24 Nov 2020 18:35:27

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:14:49
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 19:44:25
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	24 Nov 2020 18:35:27

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:14:49
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 19:44:25
User entered empty.	Megan Loughran (b) (4) (b) (4)	24 Nov 2020 18:35:27

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:14:49
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 19:44:25
User entered 'unknown (UNKNOWN)'	Megan Loughran (b) (4) (b) (4)	24 Nov 2020 18:35:27

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:14:49
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 19:44:25
User entered empty.	Megan Loughran (b) (4) (b) (4)	24 Nov 2020 18:35:27

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:14:49
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 19:44:25
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	24 Nov 2020 18:35:27

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:14:49
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 19:44:25
User entered empty.	Megan Loughran (b) (4) (b) (4)	24 Nov 2020 18:35:27

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:14:49
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 19:44:25
User entered '18 Oct 2020'	Megan Loughran (b) (4) (b) (4)	24 Nov 2020 18:35:27

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:14:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 19:44:25
User entered '0'	Megan Loughran (b) (4) (b) (4)	24 Nov 2020 18:35:27

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:14:49
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 19:44:25
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	24 Nov 2020 18:35:27

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:14:49
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 19:44:25
User entered '22 Oct 2020'	Megan Loughran (b) (4) (b) (4)	24 Nov 2020 18:35:27

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:14:49
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 19:44:25
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	24 Nov 2020 18:35:27

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:14:49
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:37
User entered empty.	System	24 Nov 2020 18:35:27

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:14:49
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:37
User entered empty.	System	24 Nov 2020 18:35:27

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:14:49
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:37
User entered empty.	System	24 Nov 2020 18:35:27

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:14:49
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:00
DataPoint Verified.		23 Mar 2021 18:36:06
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC TROMETHAMINE, PRODUCTSYNONYM: TORADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Dec 2020 09:53:20
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 Dec 2020 09:53:20
Data point term sent to Coder	System	24 Dec 2020 22:49:04
Data point term sent to Coder	System	24 Dec 2020 22:42:01
User entered 'Toradol'	Nancy Tang (b) (4)	24 Dec 2020 22:41:13

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:14:49
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:00
DataPoint Verified.		23 Mar 2021 18:36:06
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'No (N)'	Nancy Tang (b) (4)	24 Dec 2020 22:41:13

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:14:49
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:00
DataPoint Verified.		23 Mar 2021 18:36:06
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Back pain related to COVID19' reason for change: Data Entry Error	Nancy Tang (b) (4)	24 Dec 2020 22:48:16
User entered 'Covid19'	Nancy Tang (b) (4)	24 Dec 2020 22:41:13

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:14:49
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:00
DataPoint Verified.		23 Mar 2021 18:36:06
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'UNK'	Nancy Tang (b) (4)	24 Dec 2020 22:41:13

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:14:49
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:00
DataPoint Verified.		23 Mar 2021 18:36:06
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	29 Dec 2020 05:28:27
Query 'Data is required. Please complete.' answered with 'Unknown dosage per subject' (Site from System).	Nancy Tang (b) (4)	24 Dec 2020 22:41:42
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Dec 2020 22:41:13
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:41:13

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:14:49
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:00
DataPoint Verified.		23 Mar 2021 18:36:06
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:41:13

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:14:49
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:00
DataPoint Verified.		23 Mar 2021 18:36:06
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'once (ONCE)'	Nancy Tang (b) (4)	24 Dec 2020 22:41:13

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US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:14:49
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:00
DataPoint Verified.		23 Mar 2021 18:36:06
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:41:13

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:14:49
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:00
DataPoint Verified.		23 Mar 2021 18:36:06
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Oral (ORAL)'	Nancy Tang (b) (4)	24 Dec 2020 22:41:13

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:14:49
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:00
DataPoint Verified.		23 Mar 2021 18:36:06
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:41:13

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:14:49
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:00
DataPoint Verified.		23 Mar 2021 18:36:06
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '19 Dec 2020'	Nancy Tang (b) (4)	24 Dec 2020 22:41:13

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:14:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:00
DataPoint Verified.		23 Mar 2021 18:36:06
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '0'	Nancy Tang (b) (4)	24 Dec 2020 22:41:13

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:14:49
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:00
DataPoint Verified.		23 Mar 2021 18:36:06
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'No (N)'	Nancy Tang (b) (4)	24 Dec 2020 22:41:13

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:14:49
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:00
DataPoint Verified.		23 Mar 2021 18:36:06
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '19 Dec 2020'	Nancy Tang (b) (4)	24 Dec 2020 22:41:13

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:14:49
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:00
DataPoint Verified.		23 Mar 2021 18:36:06
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'No (N)'	Nancy Tang (b) (4)	24 Dec 2020 22:41:13

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:14:49
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:00
User entered empty.	System	24 Dec 2020 22:41:13

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:14:49
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:00
User entered empty.	System	24 Dec 2020 22:41:13

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:14:49
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:00
User entered empty.	System	24 Dec 2020 22:41:13

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:14:49
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:18
DataPoint Verified.		23 Mar 2021 18:29:34
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: CODEINE PHOSPHATE;PARACETAMOL, PRODUCTSYNONYM: TYLENOL W/CODEINE NO. 3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Dec 2020 09:51:20
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 Dec 2020 09:51:20
Data point term sent to Coder	System	24 Dec 2020 22:43:01
User entered 'Tylenol with Codeine #3'	Nancy Tang (b) (4)	24 Dec 2020 22:42:55

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:14:49
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:18
DataPoint Verified.		23 Mar 2021 18:29:34
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'No (N)'	Nancy Tang (b) (4)	24 Dec 2020 22:42:55

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:14:49
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:18
DataPoint Verified.		23 Mar 2021 18:29:34
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Covid19'	Nancy Tang (b) (4)	24 Dec 2020 22:42:55

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:14:49
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:18
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	26 Mar 2021 21:17:34
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) (6)	24 Mar 2021 17:13:41
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:29:34
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 'dose added' (Site from DM).	Megan Loughran (b) (4) (b) (4)	22 Mar 2021 23:12:35
Signature has been broken.	Megan Loughran (b) (4) (b) (4)	22 Mar 2021 23:12:28
User entered '300/30' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	22 Mar 2021 23:12:28
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)	26 Feb 2021 00:19:58
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '1'	Nancy Tang (b) (4)	24 Dec 2020 22:42:55

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:14:49
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:18
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	26 Mar 2021 21:17:34
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:29:34
Signature has been broken.	Megan Loughran (b) (4) (b) (4)	22 Mar 2021 23:12:28
User entered 'mg (mg)' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	22 Mar 2021 23:12:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'tablet (TABLET)'	Nancy Tang (b) (4)	24 Dec 2020 22:42:55

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:14:49
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:18
DataPoint Verified.		23 Mar 2021 18:29:34
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:42:55

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:14:49
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:18
DataPoint Verified.		23 Mar 2021 18:29:34
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'as needed (PRN)'	Nancy Tang (b) (4)	24 Dec 2020 22:42:55

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:14:49
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:18
DataPoint Verified.		23 Mar 2021 18:29:34
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:42:55

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:14:49
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:18
DataPoint Verified.		23 Mar 2021 18:29:34
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Oral (ORAL)'	Nancy Tang (b) (4)	24 Dec 2020 22:42:55

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:14:49
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:18
DataPoint Verified.		23 Mar 2021 18:29:34
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:42:55

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:14:49
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:18
DataPoint Verified.		23 Mar 2021 18:29:34
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '19 Dec 2020'	Nancy Tang (b) (4)	24 Dec 2020 22:42:55

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:14:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:18
DataPoint Verified.		23 Mar 2021 18:29:34
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '0'	Nancy Tang (b) (4)	24 Dec 2020 22:42:55

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:14:49
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:18
DataPoint Verified.		23 Mar 2021 18:29:34
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'No (N)' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:07:20
User entered 'Yes (Y)'	Nancy Tang (b) (4)	24 Dec 2020 22:42:55

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:14:49
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:18
DataPoint Verified.		23 Mar 2021 18:29:34
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '22 Dec 2020' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:07:20
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:42:55

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:14:49
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:18
DataPoint Verified.		23 Mar 2021 18:29:34
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'No (N)'	Nancy Tang (b) (4)	24 Dec 2020 22:42:55

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:14:49
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:18
User entered empty.	System	24 Dec 2020 22:42:55

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:14:49
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:18
User entered empty.	System	24 Dec 2020 22:42:55

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:14:49
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:18
User entered empty.	System	24 Dec 2020 22:42:55

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:14:49
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:29:58
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Dec 2020 09:57:20
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 Dec 2020 09:57:20
Data point term sent to Coder	System	24 Dec 2020 22:44:02
User entered 'Naproxen'	Nancy Tang (b) (4)	24 Dec 2020 22:44:00

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:14:49
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:29:58
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'No (N)'	Nancy Tang (b) (4)	24 Dec 2020 22:44:00

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US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:14:49
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:29:58
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'COVID19'	Nancy Tang (b) (4)	24 Dec 2020 22:44:00

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:14:49
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:29:58
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '250'	Nancy Tang (b) (4)	24 Dec 2020 22:44:00

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:14:49
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:29:58
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'mg (mg)'	Nancy Tang (b) (4)	24 Dec 2020 22:44:00

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:14:49
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:29:58
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:44:00

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:14:49
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:29:58
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'as needed (PRN)'	Nancy Tang (b) (4)	24 Dec 2020 22:44:00

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:14:49
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:29:58
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:44:00

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:14:49
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:29:58
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Oral (ORAL)'	Nancy Tang (b) (4)	24 Dec 2020 22:44:00

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:14:49
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:29:58
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:44:00

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:14:49
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:29:58
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '19 Dec 2020'	Nancy Tang (b) (4)	24 Dec 2020 22:44:00

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:14:49
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:29:58
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '0'	Nancy Tang (b) (4)	24 Dec 2020 22:44:00

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:14:49
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:29:58
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Yes (Y)'	Nancy Tang (b) (4)	24 Dec 2020 22:44:00

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:14:49
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:29:58
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:44:00

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:14:49
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:29:58
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'No (N)'	Nancy Tang (b) (4)	24 Dec 2020 22:44:00

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US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:14:49
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Dec 2020 22:44:00

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:14:49
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Dec 2020 22:44:00

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:14:49
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Dec 2020 22:44:00

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:14:49
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:23
DataPoint Verified.		23 Mar 2021 18:30:41
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Dec 2020 09:46:19
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 Dec 2020 09:46:19
Data point term sent to Coder	System	24 Dec 2020 22:49:06
Data point term sent to Coder	System	24 Dec 2020 22:47:02
User entered 'Methocarbamol'	Nancy Tang (b) (4)	24 Dec 2020 22:46:24

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:14:49
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:23
DataPoint Verified.		23 Mar 2021 18:30:43
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'No (N)'	Nancy Tang (b) (4)	24 Dec 2020 22:46:24

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:14:49
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:23
DataPoint Verified.		23 Mar 2021 18:30:46
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Body Aches related to Covid19' reason for change: Data Entry Error	Nancy Tang (b) (4)	24 Dec 2020 22:48:41
User entered 'Body aches'	Nancy Tang (b) (4)	24 Dec 2020 22:46:24

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:14:49
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:23
DataPoint Verified.		23 Mar 2021 18:30:49
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '500'	Nancy Tang (b) (4)	24 Dec 2020 22:46:24

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:14:49
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:23
DataPoint Verified.		23 Mar 2021 18:30:51
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'mg (mg)'	Nancy Tang (b) (4)	24 Dec 2020 22:46:24

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:14:49
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:23
DataPoint Verified.		23 Mar 2021 18:30:53
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:46:24

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:14:49
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:23
DataPoint Verified.		23 Mar 2021 18:30:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'other (OTHER)'	Nancy Tang (b) (4)	24 Dec 2020 22:46:24

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:14:49
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:23
DataPoint Verified.		23 Mar 2021 18:30:58
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'every 4 hours as needed for 4 days'	Nancy Tang (b) (4)	24 Dec 2020 22:46:24

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:14:49
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:23
DataPoint Verified.		23 Mar 2021 18:31:00
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Oral (ORAL)'	Nancy Tang (b) (4)	24 Dec 2020 22:46:24

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:14:49
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:23
DataPoint Verified.		23 Mar 2021 18:31:03
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:46:24

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:14:49
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:23
DataPoint Verified.		23 Mar 2021 18:31:05
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '20 Dec 2020'	Nancy Tang (b) (4)	24 Dec 2020 22:46:24

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:14:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:23
DataPoint Verified.		23 Mar 2021 18:31:07
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '0'	Nancy Tang (b) (4)	24 Dec 2020 22:46:24

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:14:49
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:23
DataPoint Verified.		23 Mar 2021 18:31:30
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'No (N)'	Nancy Tang (b) (4)	24 Dec 2020 22:46:24

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:14:49
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:23
DataPoint Verified.		23 Mar 2021 18:31:33
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '24 Dec 2020'	Nancy Tang (b) (4)	24 Dec 2020 22:46:24

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US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:14:49
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:23
DataPoint Verified.		23 Mar 2021 18:31:35
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'No (N)'	Nancy Tang (b) (4)	24 Dec 2020 22:46:24

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:14:49
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:23
User entered empty.	System	24 Dec 2020 22:46:24

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:14:49
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:23
User entered empty.	System	24 Dec 2020 22:46:24

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:14:49
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:23
User entered empty.	System	24 Dec 2020 22:46:24

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:14:49
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:27
DataPoint Verified.		23 Mar 2021 18:32:26
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Dec 2020 22:48:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Dec 2020 22:48:29
Data point term sent to Coder	System	24 Dec 2020 22:48:03
User entered 'Tylenol'	Nancy Tang (b) (4)	24 Dec 2020 22:47:06

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:14:49
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:27
DataPoint Verified.		23 Mar 2021 18:32:26
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'No (N)'	Nancy Tang (b) (4)	24 Dec 2020 22:47:06

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:14:49
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:27
DataPoint Verified.		23 Mar 2021 18:32:26
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'FEVERS related to Covid19' reason for change: Data Entry Error	Nancy Tang (b) (4)	24 Dec 2020 22:47:48
User entered 'fevers'	Nancy Tang (b) (4)	24 Dec 2020 22:47:06

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:14:49
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:27
DataPoint Verified.		23 Mar 2021 18:32:26
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '500'	Nancy Tang (b) (4)	24 Dec 2020 22:47:06

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:14:49
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:27
DataPoint Verified.		23 Mar 2021 18:32:26
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'mg (mg)'	Nancy Tang (b) (4)	24 Dec 2020 22:47:06

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:14:49
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:27
DataPoint Verified.		23 Mar 2021 18:32:26
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:47:06

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:14:49
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:27
DataPoint Verified.		23 Mar 2021 18:32:26
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'as needed (PRN)'	Nancy Tang (b) (4)	24 Dec 2020 22:47:06

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:14:49
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:27
DataPoint Verified.		23 Mar 2021 18:32:26
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:47:06

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:14:49
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:27
DataPoint Verified.		23 Mar 2021 18:32:26
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Oral (ORAL)'	Nancy Tang (b) (4)	24 Dec 2020 22:47:06

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:14:49
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:27
DataPoint Verified.		23 Mar 2021 18:32:26
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:47:06

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:14:49
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:27
DataPoint Verified.		23 Mar 2021 18:32:26
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '24 Dec 2020'	Nancy Tang (b) (4)	24 Dec 2020 22:47:06

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:14:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:27
DataPoint Verified.		23 Mar 2021 18:32:26
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '0'	Nancy Tang (b) (4)	24 Dec 2020 22:47:06

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:14:49
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:27
DataPoint Verified.		23 Mar 2021 18:32:26
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'No (N)' reason for change: New Information	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:15:22
User entered 'Yes (Y)'	Nancy Tang (b) (4)	24 Dec 2020 22:47:06

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:14:49
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:27
DataPoint Verified.		23 Mar 2021 18:32:26
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '11 Jan 2021' reason for change: New Information	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:15:22
User entered empty.	Nancy Tang (b) (4)	24 Dec 2020 22:47:06

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US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:14:49
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:27
DataPoint Verified.		23 Mar 2021 18:32:26
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'No (N)'	Nancy Tang (b) (4)	24 Dec 2020 22:47:06

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:14:49
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:27
User entered empty.	System	24 Dec 2020 22:47:06

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:14:49
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:27
User entered empty.	System	24 Dec 2020 22:47:06

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:14:49
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:27
User entered empty.	System	24 Dec 2020 22:47:06

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:14:49
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:56
DataPoint Verified.		23 Mar 2021 18:33:32
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OPIUM ALKALOIDS AND DERIVATIVES, PRODUCT: CODEINE PHOSPHATE;PROMETHAZINE HYDROCHLORIDE, PRODUCTSYNONYM: PROMETHAZINE WITH CODEINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 22:21:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 22:21:21
Data point term sent to Coder	System	30 Dec 2020 22:20:17
User entered 'Promethazine with codeine'	Nancy Tang (b) (4)	30 Dec 2020 22:19:37

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:14:49
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:56
DataPoint Verified.		23 Mar 2021 18:33:32
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'No (N)'	Nancy Tang (b) (4)	30 Dec 2020 22:19:37

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:14:49
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:56
DataPoint Verified.		23 Mar 2021 18:33:32
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'nausea with cough'	Nancy Tang (b) (4)	30 Dec 2020 22:19:37

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:14:49
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:56
DataPoint Verified.		23 Mar 2021 18:33:32
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '5'	Nancy Tang (b) (4)	30 Dec 2020 22:19:37

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:14:49
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:56
DataPoint Verified.		23 Mar 2021 18:33:32
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'mL (mL)'	Nancy Tang (b) (4)	30 Dec 2020 22:19:37

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:14:49
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:56
DataPoint Verified.		23 Mar 2021 18:33:32
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Nancy Tang (b) (4)	30 Dec 2020 22:19:37

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:14:49
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:56
DataPoint Verified.		23 Mar 2021 18:33:32
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'as needed (PRN)'	Nancy Tang (b) (4)	30 Dec 2020 22:19:37

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:14:49
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:56
DataPoint Verified.		23 Mar 2021 18:33:32
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Nancy Tang (b) (4)	30 Dec 2020 22:19:37

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:14:49
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:56
DataPoint Verified.		23 Mar 2021 18:33:32
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Oral (ORAL)'	Nancy Tang (b) (4)	30 Dec 2020 22:19:37

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:14:49
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:56
DataPoint Verified.		23 Mar 2021 18:33:32
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Nancy Tang (b) (4)	30 Dec 2020 22:19:37

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:14:49
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:56
DataPoint Verified.		23 Mar 2021 18:33:32
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '29 Dec 2020'	Nancy Tang (b) (4)	30 Dec 2020 22:19:37

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:14:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:56
DataPoint Verified.		23 Mar 2021 18:33:32
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '0'	Nancy Tang (b) (4)	30 Dec 2020 22:19:37

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:14:49
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:56
DataPoint Verified.		23 Mar 2021 18:33:32
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'No (N)' reason for change: New Information	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:19:15
User entered 'Yes (Y)'	Nancy Tang (b) (4)	30 Dec 2020 22:19:37

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:14:49
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:56
DataPoint Verified.		23 Mar 2021 18:33:32
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '11 Jan 2021' reason for change: New Information	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:19:15
User entered empty.	Nancy Tang (b) (4)	30 Dec 2020 22:19:37

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:14:49
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:56
DataPoint Verified.		23 Mar 2021 18:33:32
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'No (N)'	Nancy Tang (b) (4)	30 Dec 2020 22:19:37

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:14:49
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:56
User entered empty.	System	30 Dec 2020 22:19:37

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:14:49
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:56
User entered empty.	System	30 Dec 2020 22:19:37

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:14:49
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:56
User entered empty.	System	30 Dec 2020 22:19:37

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:14:49
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:00
DataPoint Verified.		23 Mar 2021 18:33:57
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE PROPIONATE;SALMETEROL XINAFOATE, PRODUCTSYNONYM: ADVAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 23:52:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 23:52:23
Data point term sent to Coder	System	30 Dec 2020 23:51:29
Query 'For coding purposes, please check and confirm brand name and active ingredients as they do not match as reported, and update the term accordingly' canceled (Site from System).	Coder Import (b) (4) (b) (4)	30 Dec 2020 23:51:25
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE PROPIONATE;SALMETEROL XINAFOATE, PRODUCTSYNONYM: ADVAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 23:51:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 23:51:22
User opened query 'For coding purposes, please check and confirm brand name and active ingredients as they do not match as reported, and update the term accordingly' (Site from System).	Coder Import (b) (4) (b) (4)	30 Dec 2020 22:36:22

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:14:49
Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: METHYLPREDNISOLONE SODIUM SUCCINATE, PRODUCTSYNONYM: SOLUMEDROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 22:34:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 22:34:22
Data point term sent to Coder	System	30 Dec 2020 22:24:29
User entered 'Advair (fluticasone 500mcg, solumedrol 50mcg)'	Nancy Tang (b) (4)	30 Dec 2020 22:24:23

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:14:49
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:00
DataPoint Verified.		23 Mar 2021 18:33:57
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'No (N)'	Nancy Tang (b) (4)	30 Dec 2020 22:24:23

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:14:49
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:00
DataPoint Verified.		23 Mar 2021 18:33:57
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'cough'	Nancy Tang (b) (4)	30 Dec 2020 22:24:23

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:14:49
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:00
DataPoint Verified.		23 Mar 2021 18:33:57
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '500/50'	Nancy Tang (b) (4)	30 Dec 2020 22:24:23

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:14:49
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:00
DataPoint Verified.		23 Mar 2021 18:33:57
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'ug (ug)' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:19:47
User entered 'puff (PUFF)'	Nancy Tang (b) (4)	30 Dec 2020 22:24:23

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:14:49
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:00
DataPoint Verified.		23 Mar 2021 18:33:57
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Nancy Tang (b) (4)	30 Dec 2020 22:24:23

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:14:49
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:00
DataPoint Verified.		23 Mar 2021 18:33:57
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'twice daily (BID)'	Nancy Tang (b) (4)	30 Dec 2020 22:24:23

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:14:49
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:00
DataPoint Verified.		23 Mar 2021 18:33:57
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Nancy Tang (b) (4)	30 Dec 2020 22:24:23

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US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:14:49
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:00
DataPoint Verified.		23 Mar 2021 18:33:57
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Nancy Tang (b) (4)	30 Dec 2020 22:24:23

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:14:49
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:00
DataPoint Verified.		23 Mar 2021 18:33:57
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Nancy Tang (b) (4)	30 Dec 2020 22:24:23

FDA-CBER-2022-1614-2895986

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:14:49
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:00
DataPoint Verified.		23 Mar 2021 18:33:57
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '30 Dec 2020'	Nancy Tang (b) (4)	30 Dec 2020 22:24:23

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:14:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:00
DataPoint Verified.		23 Mar 2021 18:33:57
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '0'	Nancy Tang (b) (4)	30 Dec 2020 22:24:23

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:14:49
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:00
DataPoint Verified.		23 Mar 2021 18:33:57
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'No (N)' reason for change: New Information	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:19:59
User entered 'Yes (Y)'	Nancy Tang (b) (4)	30 Dec 2020 22:24:23

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:14:49
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:00
DataPoint Verified.		23 Mar 2021 18:33:57
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '11 Jan 2021' reason for change: New Information	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:19:59
User entered empty.	Nancy Tang (b) (4)	30 Dec 2020 22:24:23

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US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:14:49
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:00
DataPoint Verified.		23 Mar 2021 18:33:57
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'No (N)'	Nancy Tang (b) (4)	30 Dec 2020 22:24:23

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:14:49
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:00
User entered '2'	System	30 Dec 2020 22:24:23

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:14:49
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:00
User entered '1'	System	30 Dec 2020 22:24:23

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:14:49
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:00
User entered '804 (804)'	System	30 Dec 2020 22:24:23

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:14:49
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:20
DataPoint Verified.		23 Mar 2021 18:34:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 21:41:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 21:41:23
Data point term sent to Coder	System	29 Jan 2021 20:14:11
User entered 'ibuprofen'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:13:46

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:14:49
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:20
DataPoint Verified.		23 Mar 2021 18:34:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:13:46

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:14:49
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:20
DataPoint Verified.		23 Mar 2021 18:34:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'fever, headache secondary to covid 19'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:13:46

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:14:49
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:20
DataPoint Verified.		23 Mar 2021 18:34:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '400'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:13:46

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:14:49
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:20
DataPoint Verified.		23 Mar 2021 18:34:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:13:46

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:14:49
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:20
DataPoint Verified.		23 Mar 2021 18:34:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:13:46

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:14:49
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:20
DataPoint Verified.		23 Mar 2021 18:34:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'as needed (PRN)'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:13:46

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US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:14:49
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:20
DataPoint Verified.		23 Mar 2021 18:34:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:13:46

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:14:49
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:20
DataPoint Verified.		23 Mar 2021 18:34:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:13:46

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:14:49
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:20
DataPoint Verified.		23 Mar 2021 18:34:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:13:46

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:14:49
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:20
DataPoint Verified.		23 Mar 2021 18:34:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '25 Dec 2020'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:13:46

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:14:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:20
DataPoint Verified.		23 Mar 2021 18:34:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '0'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:13:46

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:14:49
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:20
DataPoint Verified.		23 Mar 2021 18:34:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:13:46

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:14:49
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:20
DataPoint Verified.		23 Mar 2021 18:34:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '11 Jan 2021'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:13:46

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:14:49
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:20
DataPoint Verified.		23 Mar 2021 18:34:27
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:13:46

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:14:49
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:20
User entered empty.	System	29 Jan 2021 20:13:46

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:14:49
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:20
User entered empty.	System	29 Jan 2021 20:13:46

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:14:49
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:20
User entered empty.	System	29 Jan 2021 20:13:46

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:14:49
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:24
DataPoint Verified.		23 Mar 2021 18:35:17
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Jan 2021 12:01:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Jan 2021 12:01:19
Data point term sent to Coder	System	29 Jan 2021 20:15:15
User entered 'zofran'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:14:45

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:14:49
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:24
DataPoint Verified.		23 Mar 2021 18:35:17
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:14:45

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:14:49
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:24
DataPoint Verified.		23 Mar 2021 18:35:17
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'nausea secondary to covid19'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:14:45

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:14:49
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:24
DataPoint Verified.		23 Mar 2021 18:35:17
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '4'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:14:45

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:14:49
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:24
DataPoint Verified.		23 Mar 2021 18:35:17
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:14:45

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:14:49
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:24
DataPoint Verified.		23 Mar 2021 18:35:17
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:14:45

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:14:49
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:24
DataPoint Verified.		23 Mar 2021 18:35:17
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'as needed (PRN)'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:14:45

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:14:49
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:24
DataPoint Verified.		23 Mar 2021 18:35:17
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:14:45

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:14:49
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:24
DataPoint Verified.		23 Mar 2021 18:35:17
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:14:45

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US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:14:49
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:24
DataPoint Verified.		23 Mar 2021 18:35:17
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:14:45

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:14:49
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:24
DataPoint Verified.		23 Mar 2021 18:35:17
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '26 Dec 2020'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:14:45

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:14:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:24
DataPoint Verified.		23 Mar 2021 18:35:17
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '0'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:14:45

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:14:49
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:24
DataPoint Verified.		23 Mar 2021 18:35:17
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:14:45

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:14:49
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:24
DataPoint Verified.		23 Mar 2021 18:35:17
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '26 Dec 2020'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:14:45

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:14:49
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:24
DataPoint Verified.		23 Mar 2021 18:35:17
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:14:45

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:14:49
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:24
User entered empty.	System	29 Jan 2021 20:14:45

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:14:49
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:24
User entered empty.	System	29 Jan 2021 20:14:45

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:14:49
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:37:24
User entered empty.	System	29 Jan 2021 20:14:45

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:14:49
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:38:04
DataPoint Verified.		23 Mar 2021 18:35:11
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 20:19:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 20:19:22
Data point term sent to Coder	System	29 Jan 2021 20:18:16
User entered 'mucinex'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:18:13

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:14:49
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:38:04
DataPoint Verified.		23 Mar 2021 18:35:11
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:18:13

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:14:49
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:38:04
DataPoint Verified.		23 Mar 2021 18:35:11
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'congestion secondary to covid19'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:18:13

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:14:49
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:38:04
DataPoint Verified.		23 Mar 2021 18:35:11
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '600'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:18:13

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:14:49
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:38:04
DataPoint Verified.		23 Mar 2021 18:35:11
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:18:13

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:14:49
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:38:04
DataPoint Verified.		23 Mar 2021 18:35:11
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:18:13

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:14:49
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:38:04
DataPoint Verified.		23 Mar 2021 18:35:11
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'as needed (PRN)'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:18:13

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:14:49
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:38:04
DataPoint Verified.		23 Mar 2021 18:35:11
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:18:13

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:14:49
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:38:04
DataPoint Verified.		23 Mar 2021 18:35:11
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:18:13

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:14:49
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:38:04
DataPoint Verified.		23 Mar 2021 18:35:11
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:18:13

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:14:49
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:38:04
DataPoint Verified.		23 Mar 2021 18:35:11
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '28 Dec 2020'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:18:13

FDA-CBER-2022-1614-2896041

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:14:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:38:04
DataPoint Verified.		23 Mar 2021 18:35:11
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '0'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:18:13

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:14:49
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:38:04
DataPoint Verified.		23 Mar 2021 18:35:11
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:18:13

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:14:49
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:38:04
DataPoint Verified.		23 Mar 2021 18:35:11
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '11 Jan 2021'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:18:13

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:14:49
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:38:04
DataPoint Verified.		23 Mar 2021 18:35:11
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:18:13

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:14:49
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:38:04
User entered empty.	System	29 Jan 2021 20:18:13

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:14:49
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:38:04
User entered empty.	System	29 Jan 2021 20:18:13

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:14:49
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:38:04
User entered empty.	System	29 Jan 2021 20:18:13

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:14:49
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:38:08
DataPoint Verified.		23 Mar 2021 18:35:13
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 21:14:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 21:14:23
Data point term sent to Coder	System	29 Jan 2021 20:19:18
User entered 'aspirin'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:18:47

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:14:49
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:38:08
DataPoint Verified.		23 Mar 2021 18:35:13
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:18:47

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:14:49
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:38:08
DataPoint Verified.		23 Mar 2021 18:35:13
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'fever secondary to covid19'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:18:47

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:14:49
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:38:08
DataPoint Verified.		23 Mar 2021 18:35:13
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '500'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:18:47

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:14:49
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:38:08
DataPoint Verified.		23 Mar 2021 18:35:13
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:18:47

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:14:49
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:38:08
DataPoint Verified.		23 Mar 2021 18:35:13
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:18:47

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:14:49
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:38:08
DataPoint Verified.		23 Mar 2021 18:35:13
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'as needed (PRN)'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:18:47

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:14:49
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:38:08
DataPoint Verified.		23 Mar 2021 18:35:13
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:18:47

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:14:49
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:38:08
DataPoint Verified.		23 Mar 2021 18:35:13
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:18:47

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:14:49
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:38:08
DataPoint Verified.		23 Mar 2021 18:35:13
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered empty.	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:18:47

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:14:49
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:38:08
DataPoint Verified.		23 Mar 2021 18:35:13
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '28 Dec 2020'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:18:47

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:14:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:38:08
DataPoint Verified.		23 Mar 2021 18:35:13
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '0'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:18:47

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:14:49
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:38:08
DataPoint Verified.		23 Mar 2021 18:35:13
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:18:47

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:14:49
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:38:08
DataPoint Verified.		23 Mar 2021 18:35:13
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered '11 Jan 2021'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:18:47

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:14:49
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:38:08
DataPoint Verified.		23 Mar 2021 18:35:13
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:28
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	29 Jan 2021 20:18:47

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:14:49
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:38:08
User entered empty.	System	29 Jan 2021 20:18:47

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:14:49
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:38:08
User entered empty.	System	29 Jan 2021 20:18:47

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:14:49
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:38:08
User entered empty.	System	29 Jan 2021 20:18:47

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:14:49
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	26 Mar 2021 21:17:34
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:14:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: DULAGLUTIDE, PRODUCTSYNONYM: TRULICITY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 19:15:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 19:15:33
Data point term sent to Coder	System	15 Mar 2021 19:14:59
User entered 'TRULICITY'	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:50

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:14:49
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	26 Mar 2021 21:17:34
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:14:38
User entered 'No (N)'	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:50

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:14:49
Indication

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	26 Mar 2021 21:17:34
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:14:38
User entered 'UNCONTROLLED TYPE 2 DIABETES'	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:50

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:14:49
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:02:57
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	19 Apr 2021 18:02:04
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 13:12:00
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'DATA ENTRY ERROR - CORRECT DOSE 0.75MG' (Site from DM).	Colleen McLellan (b) (4) (b) (4)	13 Apr 2021 18:46:51
DataPoint Un-verified.	Colleen McLellan (b) (4) (b) (4)	13 Apr 2021 18:46:28
Signature has been broken.	Colleen McLellan (b) (4) (b) (4)	13 Apr 2021 18:46:28
User entered '0.75' reason for change: Data Entry Error	Colleen McLellan (b) (4) (b) (4)	13 Apr 2021 18:46:28
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 03:52:15
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	26 Mar 2021 21:17:34
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:14:38
User entered '7.5'	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:50

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:14:49
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	26 Mar 2021 21:17:34
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:14:38
User entered 'mg (mg)'	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:50

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:14:49
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	26 Mar 2021 21:17:34
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:14:38
User entered empty.	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:50

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:14:49
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	26 Mar 2021 21:17:34
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:14:38
User entered 'every week (QS)'	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:50

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:14:49
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	26 Mar 2021 21:17:34
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:14:38
User entered empty.	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:50

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:14:49
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	26 Mar 2021 21:17:34
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:14:38
User entered 'Subcutaneous (SUBCUTANEOUS)'	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:50

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:14:49
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	26 Mar 2021 21:17:34
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:14:38
User entered empty.	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:50

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:14:49
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	26 Mar 2021 21:17:34
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:14:38
User entered '03 Mar 2021'	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:50

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:14:49
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	26 Mar 2021 21:17:34
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:14:38
User entered '0'	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:50

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:14:49
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:37:49
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	28 Apr 2021 23:40:00
DataPoint Un-verified.	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:22:13
Signature has been broken.	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:22:13
User entered 'No (N)' reason for change: Data Entry Error	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:22:13
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	26 Mar 2021 21:17:34
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:14:38
User entered 'Yes (Y)'	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:50

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:14:49
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:37:49
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	28 Apr 2021 23:40:00
DataPoint Un-verified.	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:22:13
Signature has been broken.	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:22:13
User entered '06 Apr 2021' reason for change: Data Entry Error	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:22:13
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	26 Mar 2021 21:17:34
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:14:38
User entered empty.	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:50

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:14:49
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	26 Mar 2021 21:17:34
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:14:38
User entered 'No (N)'	Colleen McLellan (b) (4) (b) (4)	15 Mar 2021 19:14:50

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:14:49
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	15 Mar 2021 19:14:50

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:14:49
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	15 Mar 2021 19:14:50

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:14:49
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '803 (803)'	System	15 Mar 2021 19:14:50

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:14:49
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:37:49
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	28 Apr 2021 23:40:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: DULAGLUTIDE, PRODUCTSYNONYM: TRULICITY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Apr 2021 22:24:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Apr 2021 22:24:24
Data point term sent to Coder	System	28 Apr 2021 22:23:55
User entered 'TRULICITY'	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:23:52

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:14:49
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:37:49
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	28 Apr 2021 23:40:00
User entered 'No (N)'	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:23:52

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:14:49
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:37:49
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	28 Apr 2021 23:40:00
User entered 'DIABETES TYPE 2'	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:23:52

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:14:49
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:37:49
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	28 Apr 2021 23:40:00
User entered '1.5'	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:23:52

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:14:49
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:37:49
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	28 Apr 2021 23:40:00
User entered 'mg (mg)'	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:23:52

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:14:49
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:37:49
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	28 Apr 2021 23:40:00
User entered empty.	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:23:52

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:14:49
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:37:49
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	28 Apr 2021 23:40:00
User entered 'every week (QS)'	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:23:52

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:14:49
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:37:49
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	28 Apr 2021 23:40:00
User entered empty.	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:23:52

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:14:49
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:37:49
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	28 Apr 2021 23:40:00
User entered 'Subcutaneous (SUBCUTANEOUS)'	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:23:52

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:14:49
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:37:49
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	28 Apr 2021 23:40:00
User entered empty.	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:23:52

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:14:49
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:37:49
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	28 Apr 2021 23:40:00
User entered '6 Apr 2021'	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:23:52

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:14:49
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:37:49
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	28 Apr 2021 23:40:00
User entered '0'	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:23:52

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:14:49
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:37:49
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	28 Apr 2021 23:40:00
User entered 'Yes (Y)'	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:23:52

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:14:49
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:37:49
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	28 Apr 2021 23:40:00
User entered empty.	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:23:52

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:14:49
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:37:49
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	28 Apr 2021 23:40:00
User entered 'No (N)'	Colleen McLellan (b) (4) (b) (4)	28 Apr 2021 22:23:52

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:14:49
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	28 Apr 2021 22:23:52

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:14:49
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	28 Apr 2021 22:23:52

US3642086
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:14:49
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '803 (803)'	System	28 Apr 2021 22:23:52

US3642086
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 10 Jun 2021 09:14:49
Were any concomitant procedures performed?

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 19:45:03
User entered 'No (N)'	Son Do (b) (4)	05 Oct 2020 16:37:30

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 09:14:49
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:36:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 19:55:07
User entered 'USA-US109-2020-MRNA-1273-P301000010'	System	29 Dec 2020 19:54:54

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 09:14:49
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:36:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 19:55:07
User entered 'No (N)'	System	29 Dec 2020 19:54:54

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 09:14:49
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:36:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 19:55:07
User entered 'No (N)'	System	29 Dec 2020 19:54:54

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 09:14:49
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:36:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 19:55:07
User entered 'No (N)'	System	29 Dec 2020 19:54:54

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 09:14:49
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:36:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 19:55:07
User entered 'No (N)'	System	29 Dec 2020 19:54:54

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 09:14:49
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:36:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 19:55:07
User entered 'No (N)'	System	29 Dec 2020 19:54:54

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 09:14:49
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:36:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 19:55:07
User entered 'No (N)'	System	29 Dec 2020 19:54:54

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 09:14:49
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:36:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 19:55:07
User entered 'No (N)'	System	29 Dec 2020 19:54:54

FDA-CBER-2022-1614-2896111

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 09:14:49
Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:36:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 19:55:07
User entered 'Stephen'	System	29 Dec 2020 19:54:54

FDA-CBER-2022-1614-2896112

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 09:14:49
Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:36:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 19:55:07
User entered 'Spector'	System	29 Dec 2020 19:54:54

FDA-CBER-2022-1614-2896113

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 09:14:49
Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:36:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:02:00
User entered 'US'	System	29 Dec 2020 19:55:16

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 09:14:49
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered '2'	System	14 Jan 2021 00:02:09
User entered '1'	System	29 Dec 2020 19:55:16

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 09:14:49
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:36:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 19:55:07
User entered 'USA-US109-2020-MRNA-1273-P301000010'	System	29 Dec 2020 19:54:54

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 09:14:49
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:36:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 19:55:07
User entered 'No (N)'	System	29 Dec 2020 19:54:54

FDA-CBER-2022-1614-2896117

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 09:14:49
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:36:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 19:55:07
User entered 'No (N)'	System	29 Dec 2020 19:54:54

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 09:14:49
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:36:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 19:55:07
User entered 'No (N)'	System	29 Dec 2020 19:54:54

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 09:14:49
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:36:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 19:55:07
User entered 'No (N)'	System	29 Dec 2020 19:54:54

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 09:14:49
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:36:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 19:55:07
User entered 'No (N)'	System	29 Dec 2020 19:54:54

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 09:14:49
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:36:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 19:55:07
User entered 'No (N)'	System	29 Dec 2020 19:54:54

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 09:14:49
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:36:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 19:55:07
User entered 'No (N)'	System	29 Dec 2020 19:54:54

FDA-CBER-2022-1614-2896123

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 09:14:49
Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:36:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 19:55:07
User entered 'Stephen'	System	29 Dec 2020 19:54:54

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 09:14:49
Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:36:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 19:55:07
User entered 'Spector'	System	29 Dec 2020 19:54:54

FDA-CBER-2022-1614-2896125

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 09:14:49
Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:36:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:02:00
User entered 'US'	System	29 Dec 2020 19:55:16

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 09:14:49
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered '2'	System	14 Jan 2021 00:02:09
User entered '1'	System	29 Dec 2020 19:55:16

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form (1)
Generated On: 10 Jun 2021 09:14:49
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:36:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
User entered '29/Dec/2020 14:55'	(b) (4) System	29 Dec 2020 19:55:16

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form (1)
Generated On: 10 Jun 2021 09:14:49
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)	23 Mar 2021 18:36:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 00:02:00
User entered '1'		29 Dec 2020 19:55:16

FDA-CBER-2022-1614-2896129

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 09:14:49
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:36:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 19:55:07
User entered 'USA-US109-2020-MRNA-1273-P301000010'	System	29 Dec 2020 19:54:54

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 09:14:49
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:36:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 19:55:07
User entered 'No (N)'	System	29 Dec 2020 19:54:54

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 09:14:49
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:36:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 19:55:07
User entered 'No (N)'	System	29 Dec 2020 19:54:54

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 09:14:49
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:36:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 19:55:07
User entered 'No (N)'	System	29 Dec 2020 19:54:54

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 09:14:49
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:36:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 19:55:07
User entered 'No (N)'	System	29 Dec 2020 19:54:54

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 09:14:49
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:36:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 19:55:07
User entered 'No (N)'	System	29 Dec 2020 19:54:54

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 09:14:49
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:36:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 19:55:07
User entered 'No (N)'	System	29 Dec 2020 19:54:54

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 09:14:49
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:36:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 19:55:07
User entered 'No (N)'	System	29 Dec 2020 19:54:54

FDA-CBER-2022-1614-2896137

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 09:14:49
Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:36:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 19:55:07
User entered 'Stephen'	System	29 Dec 2020 19:54:54

FDA-CBER-2022-1614-2896138

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 09:14:49
Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:36:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 19:55:07
User entered 'Spector'	System	29 Dec 2020 19:54:54

FDA-CBER-2022-1614-2896139

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 09:14:49
Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:36:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:02:00
User entered 'US'	System	29 Dec 2020 19:55:16

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 09:14:49
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered '2'	System	14 Jan 2021 00:02:09
User entered '1'	System	29 Dec 2020 19:55:16

US3642086
Folder: SAE USA-US109-2020-MRNA-1273-P301000010
Form: Safety Report Form (2)
Generated On: 10 Jun 2021 09:14:49
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:36:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:41:31
User entered '14/Jan/2021 00:02'	(b) (4) System	14 Jan 2021 00:02:09

FDA-CBER-2022-1614-2896142

US3642086

Folder: SAE USA-US109-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:14:49

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)	23 Mar 2021 18:36:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:41:31
User entered '1'	(b) (4), (b) (6)	14 Jan 2021 00:02:09